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14. ABSTRACT

Background. Restless Legs Syndrome (RLS) is a commonly under diagnosed organic cause of insomnia. There is evidence that insomnia leads to psychic distress which impacts health care utilization. **Purpose.** To examine a proposed model which links RLS to insomnia, and insomnia to reduced mental health and increased utilization. **Scope.** To estimate the prevalence of RLS, insomnia, mood disorders, and substance abuse; quantify the proportion of mood disorders and substance abuse which are attributable to RLS and insomnia; document the diagnosis of RLS and insomnia; and estimate the association of RLS and insomnia to health care utilization and health related quality of life. **Methods.** A cross-sectional survey of a representative sample of Ohio VA clients using telephone interviews and data extracted from medical records. One year follow-up of health care utilization using postal questionnaire and medical records. **Results.** 1761 Veterans were enrolled in the study. 71% completed one year follow-up. 18% of males and 28% of females reported 4 RLS symptoms; 26% of respondents reported insomnia and 25% reported daytime sleepiness. Insomnia attributable risk (AR) %'s are: RLS (22%); age 50-59 (49%); BMI>29 (27%). Daytime sleepiness AR%'s are: insomnia (27%); age 50-59 (14%);BMI>29 (12%); RLS (7%). Few diagnoses were found in medical record: RLS – 4%; insomnia – 29%; daytime sleepiness – 26%.

15. SUBJECT TERMS
Restless Legs Syndrome, Insomnia, Depression, Mood disorders, Utilization, Veterans, Epidemiology

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INTRODUCTION

Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest and when initiating sleep. The sufferer experiences an uncontrollable urge to move in order to relieve symptoms. RLS interferes with the ability to fall asleep or to maintain sleep. The resulting sleep deprivation can interfere with family life, social activities, and job performance. (1) We hypothesize that RLS has a high prevalence in the veteran community and is under diagnosed. We also hypothesize that undiagnosed and untreated RLS is associated with an unknown, but measurable proportion of the insomnia in any population. An association between insomnia and mood and anxiety disorders is well documented, as is the association between these mental health disorders and increased health care utilization. (2;3) In this research, we therefore propose an underlying model in which RLS contributes to insomnia; and insomnia contributes to diminished mental health status. Diminished mental health status in turn may lead to increased health care utilization.

The current research, which we are calling the Veterans Sleep Study, is a study of the prevalence and outcomes of RLS among patients of the Veterans Administration health care system in northern Ohio. The specific goals of the research are the following:

- To estimate the prevalence of Restless Legs Syndrome and insomnia;
- To determine in the VA population the proportion of insomnia that is attributable to RLS;
- To estimate in the VA population the strength of the association of insomnia and RLS with depression, anxiety, and substance abuse adjusting for comorbid health conditions;
- To estimate in the VA population strength of the association of insomnia and RLS with health related quality of life adjusting for comorbid conditions;
- To document the current level of diagnosis of insomnia and RLS in the VA population;
- To document the level of health care utilization at baseline interview and at one year follow-up associated with insomnia and RLS adjusting for comorbid health conditions;
- To assess the validity of the questionnaire instrument using interview by a trained clinician as the gold standard.

BODY OF REPORT

STATEMENT OF WORK

The following is the revised statement of work which was submitted on December 18, 2002 and approved by email on February 6, 2003. In April, 2004, Task 6 was added to the project. The report of our accomplishments with regard to these items follows.

Task 1: Estimate the prevalence of Restless Legs Syndrome, insomnia, mood and anxiety disorders, and substance abuse in persons who have scheduled primary care appointments at a Veterans Administration Community Based Outpatient Clinic (CBOC) in northeast Ohio. Document the current level of diagnosis of insomnia and RLS in the VA population.

a) Hire and train study personnel (Months 1-2)
b) Recruit 1914 study members at CBOC's (Months 3-8)
c) Conduct computer assisted telephone interviews with 1914 Veterans Administration clients. (Months 4-10)
d) Extract problem lists and time 1 utilization data from 1914 electronic medical records. (Months 6-12)
e) Data cleaning and analysis (Months 13-21)
f) Manuscript preparation (Months 20-24)

Task 2: Estimate in the northern Ohio VA population the strength of the association of RLS with insomnia after adjusting for comorbid health conditions. Determine the proportion of insomnia that is attributable to RLS. Estimate in the VA population the strength of the association of insomnia with depression, anxiety, and substance abuse adjusting for comorbid health conditions. Determine the proportion of psychic distress that is attributable to insomnia. Estimate in the VA population strength of the association of insomnia and RLS with health related quality of life adjusting for comorbid conditions.

a) Data analysis (Months 22–30)
b) Manuscript preparation (Months 30-36)

Task 3: Document the level of health care utilization at baseline interview and at one year follow-up associated with insomnia and RLS adjusting for comorbid health conditions.

a) Conduct interviews by mail with 1914 VA clients to determine health care utilization one year after baseline interview. (Months 16-23)
b) Extract time 2 utilization data from 1914 electronic medical records (Months 16 – 23)
c) Data entry, cleaning, and analysis (Months 18 - 30)
d) Manuscript preparation (Months 30 - 36)

Task 4: Assess the validity of the RLS questionnaire using interview by a trained clinician as the gold standard.

a) Recruit study members who are patients at the Akron CBOC and conduct clinical assessment (Months 7 - 18)
b) Analyze data (Months 19 - 20)
c) Manuscript preparation (Months 21 - 24)

Task 5: Assess the external validity of the study sample with respect to the population of VA patients who have had a visit in the past year.

a) Extract population data from electronic patient record system (Months 13-14)
b) Data analysis (Months 15-16)
c) Manuscript preparation is part of *Task 1.*

Task 6: Conduct a pilot study of an aerobic exercise intervention to improve sleep quality among RLS patients by moderating their RLS symptoms.

a) Identify RLS cases, confirm diagnosis and recruit up to 30 study members. Hire and train staff. (Months 25 – 27)
b) Compliance trial. (Month 28)
c) Conduct 3 month crossover study. 3 month intervention and 3 month control condition. (Month 29-34)
d) Analyze data and prepare report. (Month 35-36)

ACCOMPLISHMENTS IN YEAR 3 OF THE RESEARCH.

The closing date of the project was originally January 31, 2006. However, we have received a no addition cost extension of the project. This report is, therefore, a report of our accomplishments in the third year.

Task 1

Estimate the prevalence of Restless Legs Syndrome, insomnia, mood and anxiety disorders, and substance abuse in persons who have scheduled primary care appointments at a Veterans Administration Community Based Outpatient Clinic (CBOC) in northeast Ohio. Document the current level of diagnosis of insomnia and RLS in the VA population.

Contributes to research goals:

- To estimate the prevalence of Restless Legs Syndrome and insomnia;
- To document the current level of diagnosis of insomnia and RLS in the VA population;

Task 1.a Hire and train study personnel.
Task 1.b Recruit 1914 study members at Community Based Outpatient Clinics.
Task 1.c Conduct computer assisted telephone interviews with 1914 Veterans Administration clients.

Tasks 1 a –c are complete. Study member recruiting and interviewing ended in August, 2004. 1761 veterans were recruited and interviewed for the research. An additional 351 veterans were recruited and completed the consent procedure but either declined to participate when later contacted for the telephone interview or could not be reached by telephone. Table 1 shows the age and gender distribution of these study members along with the originally planned sample size in each age/ gender group.

As can be seen from Table 1, our recruiting efforts were successful in 6 of 9 age groups. We were unsuccessful in recruiting our planned numbers among men age 40 and younger, and women over age 50. When it became apparent to us that the final sample size would be reduced, we made a decision to over sample in some of the more available age/gender groups in order to retain overall statistical power.

	Age Group	Original Sample Size	Persons Recruited	Completed Interviews
Men	18-30	115	34	26
	31-40	177	82	59
	41-50	177	247	184
	51-60	236	345	282
	61-70	236	305	252
	71-80	236	350	298
	81 +	290	360	311
Women	18-50	157	221	185
	51+	290	175	164
Total		1914	2119	1761

Table 1.1 Planned and final sample size

Task 1.d Extract problem lists and Time 1 utilization data from 1914 electronic medical records.

Methods

Problem lists.

Our purpose for the data from the problem lists is case-mix adjustment. In order to obtain valid estimates of the association between sleep disorders and mental health, health related quality of life, or health care utilization, adjustment for current health status is required. Our intent had been to use the problem list file available in CPRS to do that adjustment.

A detailed examination of a sample of medical records in comparison to the problem lists indicated that the problem lists contained in the medical record were not sufficiently complete for our purposes. We have, therefore, obtained the data from all outpatient visits made by study members in the 18 months prior to the Time 1 interview. The ICD codes for all problems managed during those office visits have been merged with the previously obtained problem list data to obtain a more complete list of current health conditions at Time 1 interview. We are currently preparing that data for processing by the Johns Hopkins Case-Mix Adjustment software.

Health care utilization

The following have been obtained:

Prescription drugs.
Medications active at the time of the interview
Drug class
Date of prescription
Quantity
Number of refills
Status of prescription (active, suspended, discontinued, or expired)

Medications prescribed in a window from six months prior to the interview date to six months after the interview were identified. We were concerned that if we used only the prescriptions one month prior to the interview date that we would miss active medications taken infrequently. This information in conjunction with the quantity prescribed allows us to pick up infrequently used, but current prescriptions.

Clinic visits
Clinic visits completed in the month prior to the interview
Type of appointment: lab, radiology, primary care, mental health, physical therapy, optometry, podiatry, etc.
Date of appointment
Stop code – a VAMC indicator of the type of provider seen, multiple stops per date
CPT code – a VAMC procedure code, multiple CPT codes per stop

Hospital admissions
Admissions to VA facility in the month prior to the interview
Principle diagnosis
Date of admission
Date of discharge

Length of stay

Surgical procedures
Procedures and surgeries in the month prior to the interview
ICD code
Date of procedure or surgery
Inpatient or outpatient

Laboratory
Laboratory tests
Test code
Lab tests within the month prior to the interview
Date of tests
Test result

Radiology
Radiology visits
Imaging reports within the month prior to the interview
Type of imaging procedure
Date of test

Diagnosis of RLS and insomnia

We searched inpatient and outpatient medical record data for ICD-9 codes associated with insomnia (307.40-307.49 Specific disorders of sleep of non-organic origin and 780.50-780.59 Sleep disturbances) and RLS (333.99).

Task 1.e Data cleaning and analysis (Months 13-21)

Data cleaning of Time 1 data is complete with the exception of the newly obtained visit data which we will combine with the problem list data.

Task 1.f Manuscript preparation (Months 20-24)

Results

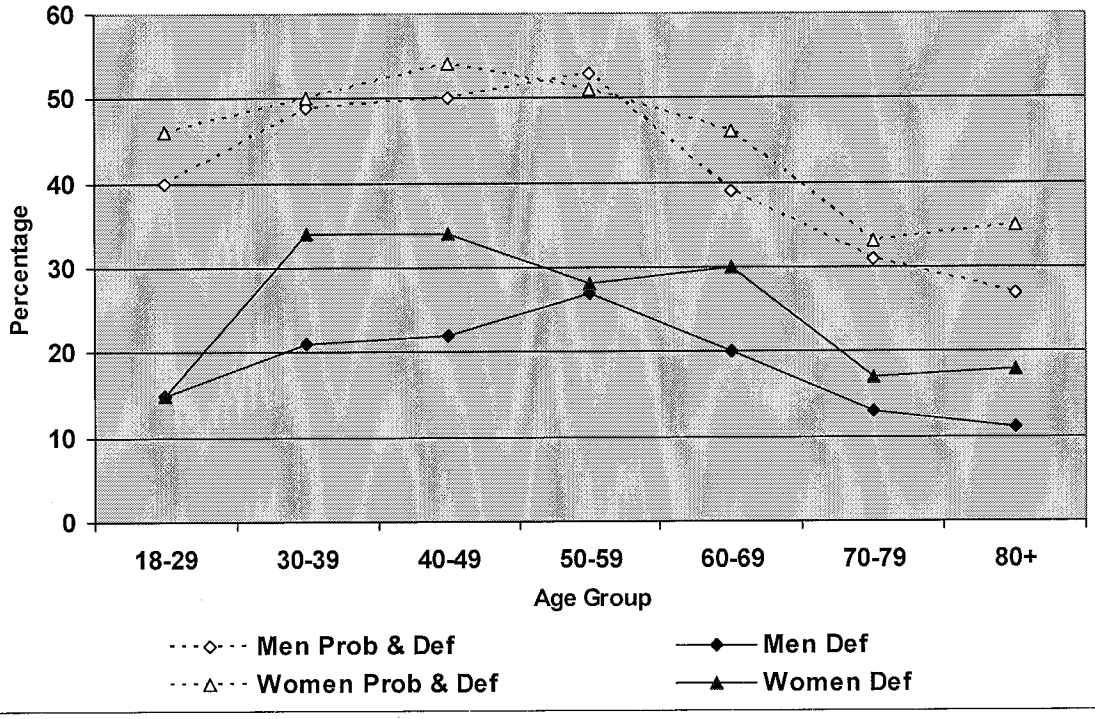
Appendix A contains detailed preliminary data tables. Table A.1 shows the descriptive characteristics of the study members. Eighty percent of the sample are men. Most are White/Caucasian (88%) although 8% are African American and 3% are Native American. Almost half (46%) of the sample have at least some college education. An alarming 80% of the sample are overweight or obese and 22% are currently smokers.

Veterans who receive primary care from the VAMC report a high prevalence of symptoms which meet the ILRSSG criteria for a diagnosis of RLS.(4) Our prevalence estimates have changed somewhat from our previous report because we have been able to refine the coding criteria for the questionnaire using the information available from the Validation Study (Task 4, below). Our current definition requires that patients report symptoms at least 2 days a month. The definition also requires that the patient either report that they either currently experience symptoms or are symptom free because of treatment. Thus, the definition requires current rather than lifetime prevalence.

The overall prevalence of definite RLS (4 symptoms required) is 18% among men and 28% among women. Our current estimates of the prevalence of probable and definite RLS are extraordinarily high – 39% among men and 48% among women. As more data are obtained from the Validation Substudy, we will have a more accurate estimate of the number of persons with probable RLS.

Figure 1 shows the prevalence of RLS by age and gender. The data from which Figures 1 to 3 were prepared can be found in Appendix A, Table A.2. Ninety-five percent confidence intervals are shown for insomnia and day time sleepiness. Among women, the prevalence of definite RLS peaks between the ages of 30 and 50; among men, prevalence peaks between ages 50 and 60. Among both men and women between the ages of 30 and 59, at least half of respondents reported some RLS symptoms at least 2 days a month.

Figure 1. Prevalence of RLS



We also found that a large proportion of RLS cases have another health condition which may be the underlying cause of their RLS symptoms (Table A.3). These conditions include: anemia, kidney disease, other movement disorders, neuropathy, and SSRI use. The high prevalence of these conditions may be partially responsible for the high prevalence of RLS in the VA population. We plan additional data analysis regarding this issue.

The prevalence of insomnia and daytime sleepiness are similarly high. Overall, 13% of study members reported moderate insomnia and 3% reported severe insomnia. Eighteen percent of respondents report moderate daytime sleepiness and 7% report severe day time sleepiness.

Figures 2 and 3 show these outcomes stratified by age and gender. While women report higher rates of RLS and insomnia, men report higher rates of excessive daytime sleepiness, especially severe sleepiness. Women age 30 to 50 also report the highest rates of insomnia. Among men, peak levels of insomnia occur in ages 40 to 60. Younger women and middle aged men report the highest levels of daytime sleepiness.

Figure 2. Prevalence of Insomnia

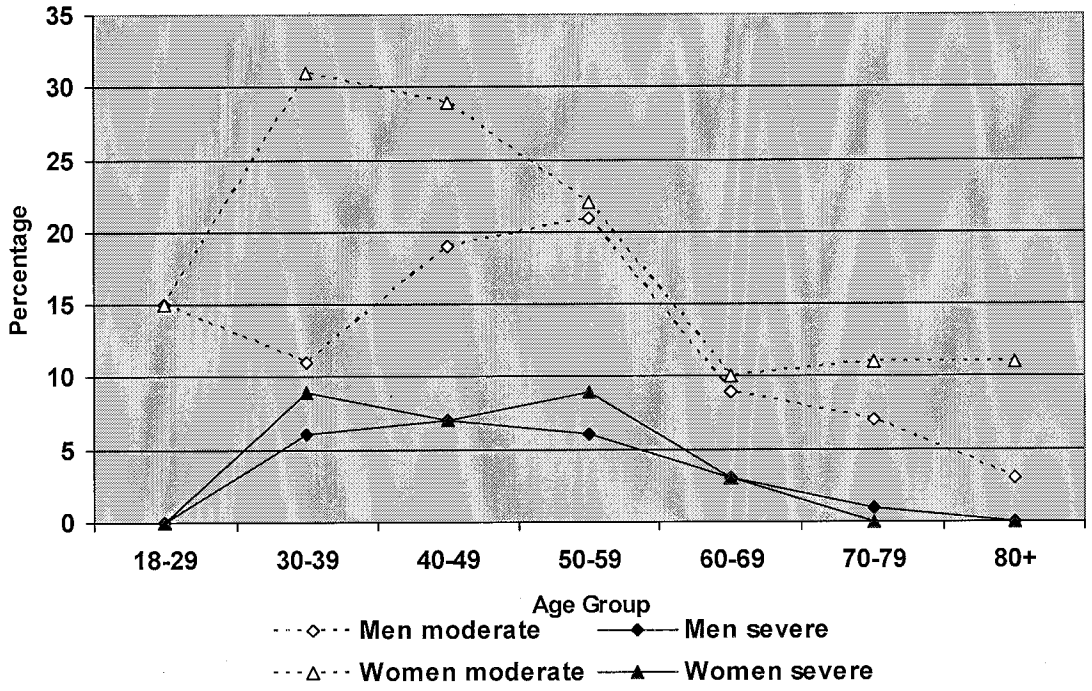
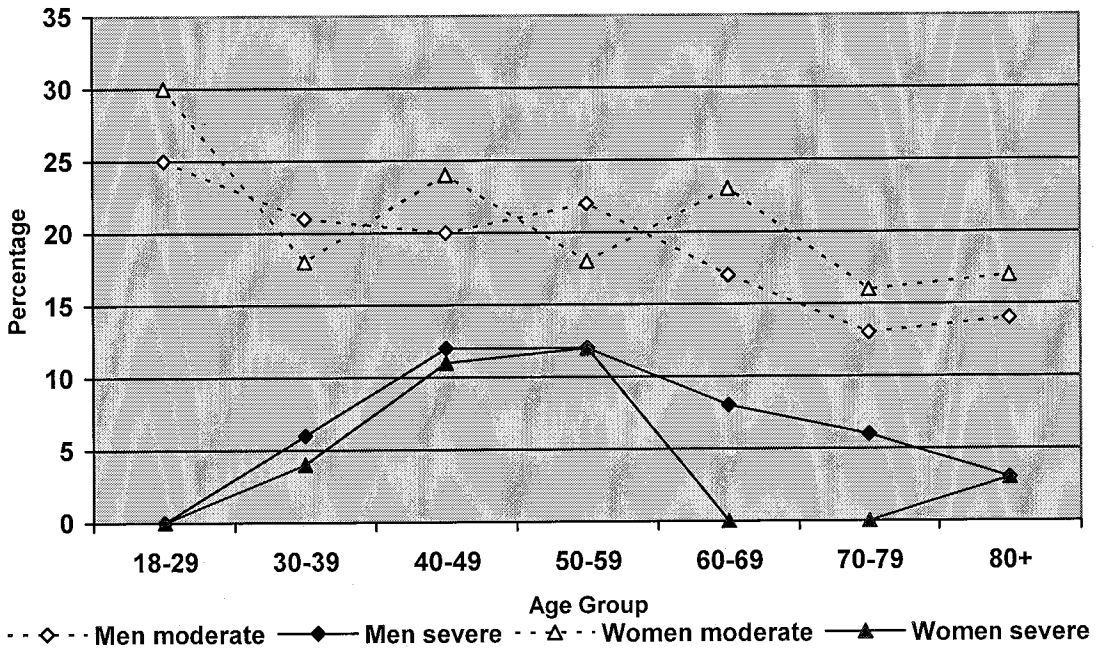


Figure 3. Prevalence of Daytime Sleepiness



In spite of the high prevalence of RLS, insomnia, and excessive daytime sleepiness found by this survey, the level of diagnosis of these conditions found in the VAMC medical records of the study members is relatively low. Four percent of persons who definitely meet the criteria for RLS and 3% of those who probably meet the criteria for RLS showed a diagnosis of RLS anywhere in their medical record. Diagnosis of insomnia and daytime sleepiness was better recorded in the VA medical record. Twenty-nine percent of respondents who reported moderate or severe insomnia had any sleep diagnosis in their medical record (26% severe; 30% moderate). Thirty-six percent of respondents who reported severe daytime sleepiness and 22% of persons who had moderate daytime sleepiness had any sleep diagnosis in their medical record. These data can be found in Tables A.4 through A.6.

Task 2:

Estimate in the northern Ohio VA population the strength of the association of RLS with insomnia after adjusting for comorbid health conditions. Determine the proportion of insomnia that is attributable to RLS. Estimate in the VA population the strength of the association of insomnia with depression, anxiety, and substance abuse adjusting for comorbid health conditions. Determine the proportion of psychic distress that is attributable to insomnia. Estimate in the VA population strength of the association of insomnia and RLS with health related quality of life adjusting for comorbid conditions.

Contributes to research goals:

- To determine in the VA population the proportion of insomnia that is attributable to RLS;
- To estimate in the VA population the strength of the association of insomnia and RLS with depression, anxiety, and substance abuse adjusting for comorbid health conditions;
- To estimate in the VA population strength of the association of insomnia and RLS with health related quality of life adjusting for comorbid conditions;

Task 2.a Data analysis.
Task 2.b Manuscript preparation.

Data analysis and manuscript preparation are underway. In these research questions, RLS and insomnia are the independent variables, mental health (measured by the CIDI) and health related quality of life (measured by the SF36) are the dependent variables, and health status (using current diagnoses from the medical record) along with age, gender, and race are potential confounders which must be controlled. The physical health scales of the SF36 may also be used to control physical health status in studies where mental health status is the health outcome.

Methods

Three case-mix adjustment methods to control confounding by health status with available software were researched: Johns-Hopkins ACG Case-Mix System, DxCG Software (DxCG, Inc.), and the Medicare Principal Inpatient Cost Group (PIP-DCG) Model. The input data for each patient that are required by all three methods are essentially the same: a patient identification code, gender, age (or DOB), and ICD-9 codes. All three methods then take this information and create various levels of patient groupings based diagnosis, which are then input, along with age and gender, into regression models to predict health care costs at the patient level.

Based on this research, the Johns-Hopkins ACG Case-Mix System (Version 6.0) was selected and a two-year research license was purchased. This software produces two levels of patient groups: diagnosis clusters called Aggregated Diagnostic Groups (ADG) and Adjusted Clinical Groups (ACG).

Every ICD-9-CM code given to a patient is placed into one of 32 ADGs (Previous versions of the software employed 36 ADGs.) Patients with multiple diagnoses can be assigned to more than one ADG. Based on the ADGs assigned and age and gender, the ACG System uses a branching algorithm to place patients into one of 93 (depending on system options set) discrete ACGs. Each patient belongs to only one ACG. Individuals within a given ACG have experienced a similar pattern of morbidity and resource consumption.

The data required for the case-mix adjustment have been obtained from the participants' problem lists and office visit data (see Task 1.d). These data are being restructured for use with the ACG Case-Mix software and the software is being configured for this study.

The primary plan for case-mix adjustment in this research is based on indicator variables for each of the ADGs (1 = present, 0 = absent), which will be included as predictors in logistic regression models. Version 6 of the ACG Case-Mix software produces two additional classifications that may be useful for case-mix adjustment: Resource Utilization Bands (RUB), which are six cost-based ACG groupings and revised Expanded Diagnosis Clusters (EDC), which are morbidity-based groupings. These will be explored for direct case-mix adjustment and as input to the development of case-mix scores (CMS). CMS are composite case-mix variables, which will be constructed using principal components analysis. Fewer CMS variables can contain much of the information in the original case-mix variables (e.g. ADG indicators, RUB, EDC).(5)

Results.

Attributable Risk analysis. Two abstracts which were presented in the summer of 2005 present some attributable risk information. These abstracts can be found in Appendix B. The first abstract is for a poster that was presented at the Associated Professional Sleep Societies meeting in Denver in June, 2005. The second abstract was presented at the Society for Epidemiologic Research in Toronto, Ontario, Canada in June, 2005. Both of these abstracts were also published in the journals of their respective professional organizations.(6;7)

The proportion of insomnia which can be attributed to RLS, gender, age, BMI, alcohol dependence and smoking is shown in Table A.7. This table also shows the proportion of excessive daytime sleepiness attributable to these factors and to insomnia. Odds ratios were calculated using a logistic model with either insomnia or daytime sleepiness as the outcome variable and all other variables are simultaneously included in the model. The prevalence of each risk factor was then used in conjunction with the Odds Ratio to estimate the attributable risk. As above, these data are provisional, pending the results of the Validation Substudy.

For insomnia, factors of greatest importance are RLS (AR% = 22%), age 50-59 (AR% = 49%), and BMI over 29 (AR% = 27%). For daytime sleepiness, factors of greatest importance are insomnia (AR% = 27%), age 50-59 (AR% = 14%), and BMI > 29 (AR% = 12%). About 7% of excessive daytime sleepiness in this sample can be attributed to RLS.

These attributable risk percent estimates do not incorporate adjustment for case-mix. Because of the relatively large proportion of RLS in our sample which may be secondary to other health conditions, we expect that adjustment for health status will be important.

Estimates of mental health status, CIDI scores. We used the CIDI short form (SF) which was developed by the World Health Organization. The CIDI contains subscales to evaluation major depression, generalized anxiety disorder, specific phobia, social phobia, agoraphobia, panic attack, alcohol dependence, and drug dependence. Each CIDI subscale yields a score which can be interpreted as the probability that a respondent with a particular response profile would meet the full diagnostic criteria for the disorder if given the full CIDI form. The full CIDI classifies respondents using the DSM-IV criteria for the above mental health conditions. The

CIDI-SF asks about symptoms within the past year and thus produces an estimate of one year prevalence.(8) (9)

Detailed data on the proportion of study members who met the DSM-IV criteria for 6 mental health conditions and 2 substance along with alcohol and drug dependence are shown in Table A.8 in Appendix A. Table 2.1 summarizes the prevalence of mental health diagnoses by gender. Diminished mental health status is common in this sample. Major depression is the most common condition (Prevalence = 20%). In addition, more than 10% of the sample suffer from generalized anxiety disorder or a specific phobia.

	Number and percent meeting CIDI criteria for DSM-IV diagnosis.					
	Males		Females		All	
	Number	%	Number	%	Number	%
Major Depression	238	17	114	33	352	20
Generalized Anxiety Disorder	136	10	65	19	201	12
Specific Phobia	170	12	79	23	249	14
Social Phobia	69	5	41	12	110	6
Agoraphobia	47	3	28	8	75	4
Panic Attack	64	5	43	12	107	6
Alcohol Dependence	44	3	11	3	55	3
Drug Dependence	14	1	8	2	22	1

Table 2.1 Prevalence of mental health conditions and substance abuse by gender.

Estimates of health related quality of life, the SF 36 scale. Figures 2.1 to 2.3 show descriptive information about the SF36 scores of the participants in the VA Sleep Study. We are using the VA SF36 scale as adapted by Kazis.(10) Figure 2.1 shows the distribution of SF36 scores obtained in the current VA Sleep Study compared to data from the Veterans Health Study and to a national SF 36 sample.(11) Participants in the VA Sleep Study appear to report better health related quality of life than participants in the Veterans Health Study. However, our data are not yet age and gender adjusted, so this conclusion may change. Both Veterans samples show poorer heath status than the US referent sample, although the patterns of better mental health than physical health status is consistent.

Figure 2.2 shows the distribution of SF36 scores from the Veterans Sleep Study stratified by gender. Men report better health related quality of life than women. Figure 2.3 shows the SF36 scores stratified by race and ethnicity. In this figure, persons who endorsed Hispanic ethnicity, also endorsed another race usually either white or African American. Differences between the racial and ethnic groups are uneven. Persons who reported white race had somewhat better mental health status. This is true for all of the mental health subscales. Persons who reported Native American race, had somewhat poorer physical health status. However, because of the small number of persons reporting Native American and Hispanic race or ethnicity, these estimates are likely to have wide confidence interval. The data from which these figures were prepared are included in Appendix A. Table A.9.

Veterans Sleep Study (VSS) Compared to the Veterans Health Study (VHS) and the National Survey of Functional Health (NSFH)

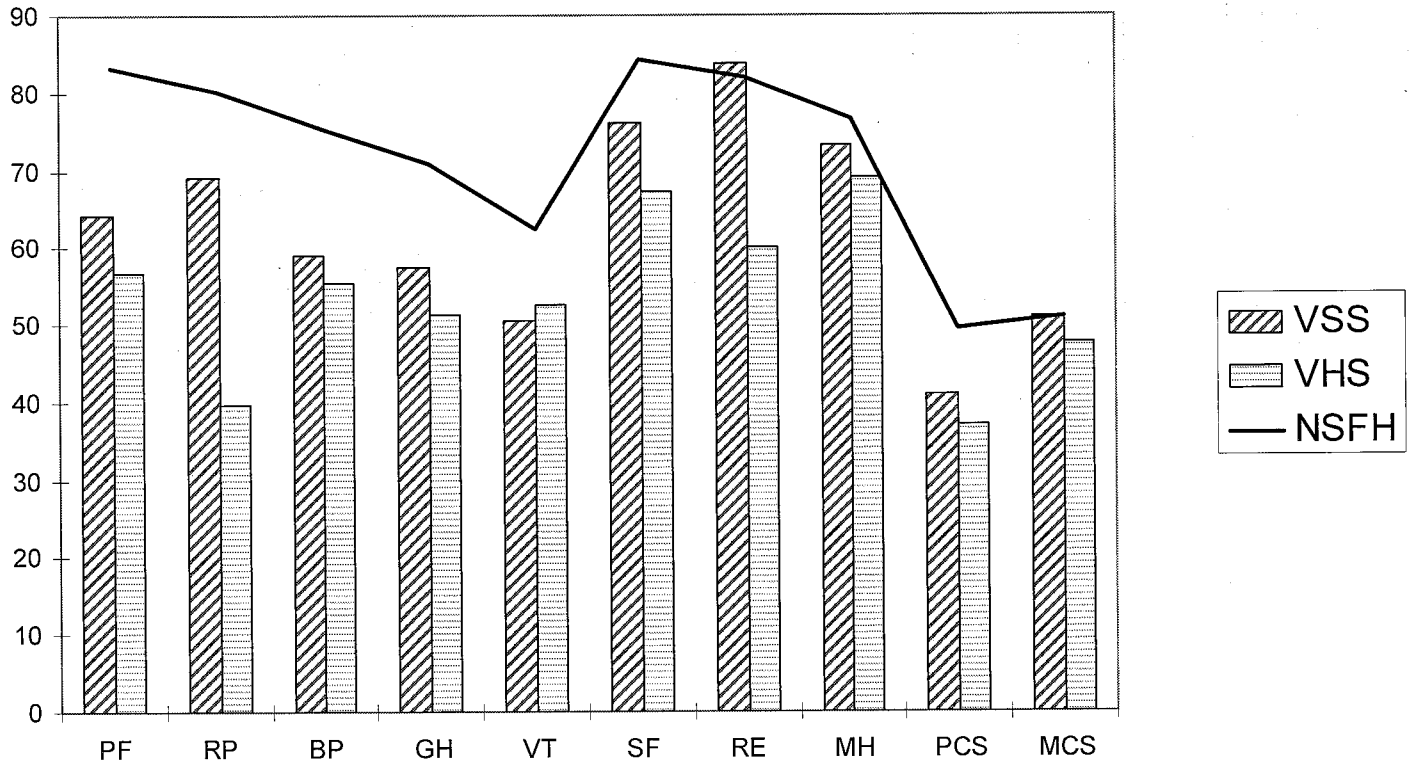


Figure 2.1. SF36 scores – Veterans Sleep Study, Veterans Health Study and national comparison sample.

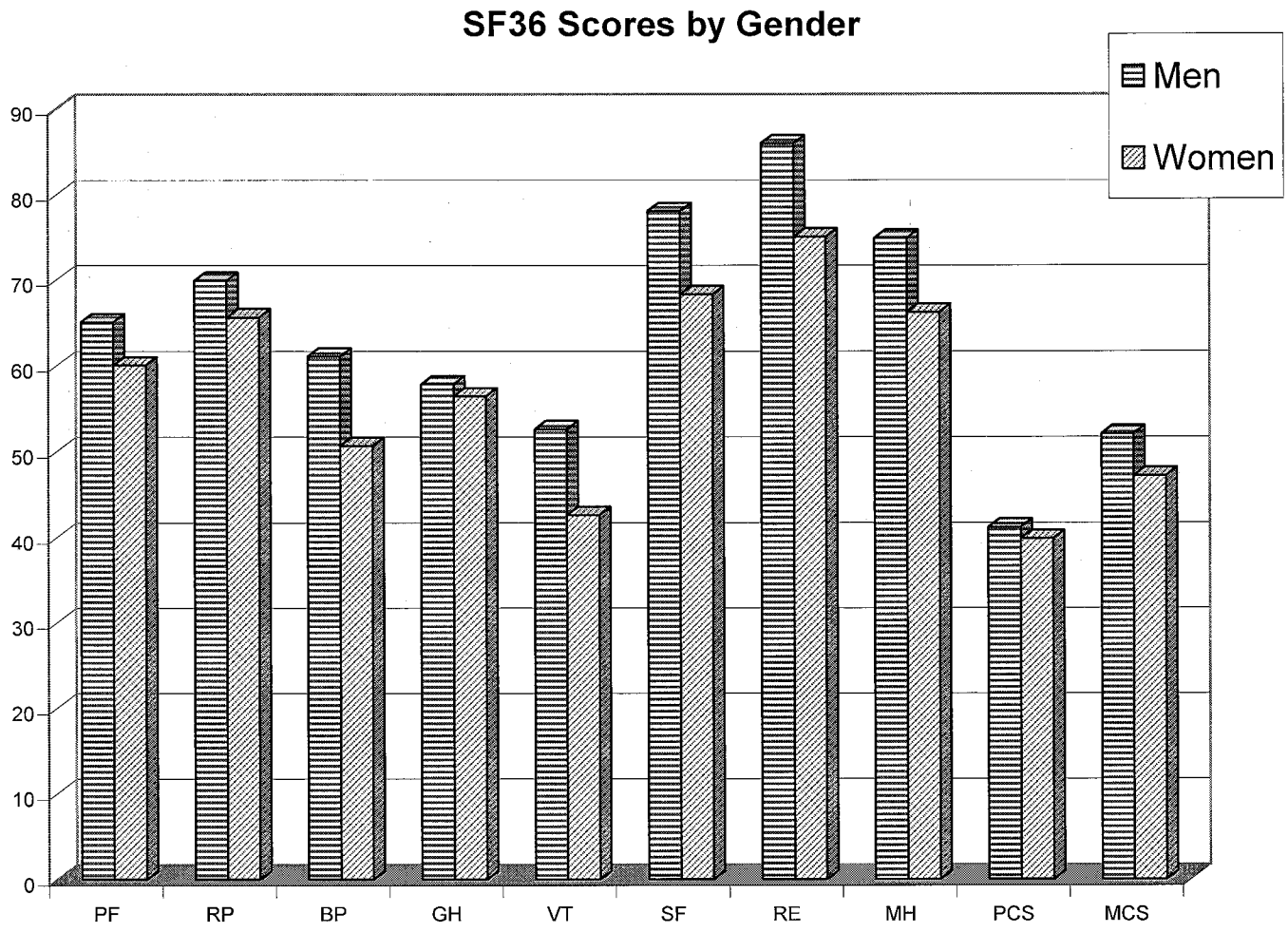


Figure 2.2 SF36 scores of participants in the Veterans Sleep Study, stratified by gender.

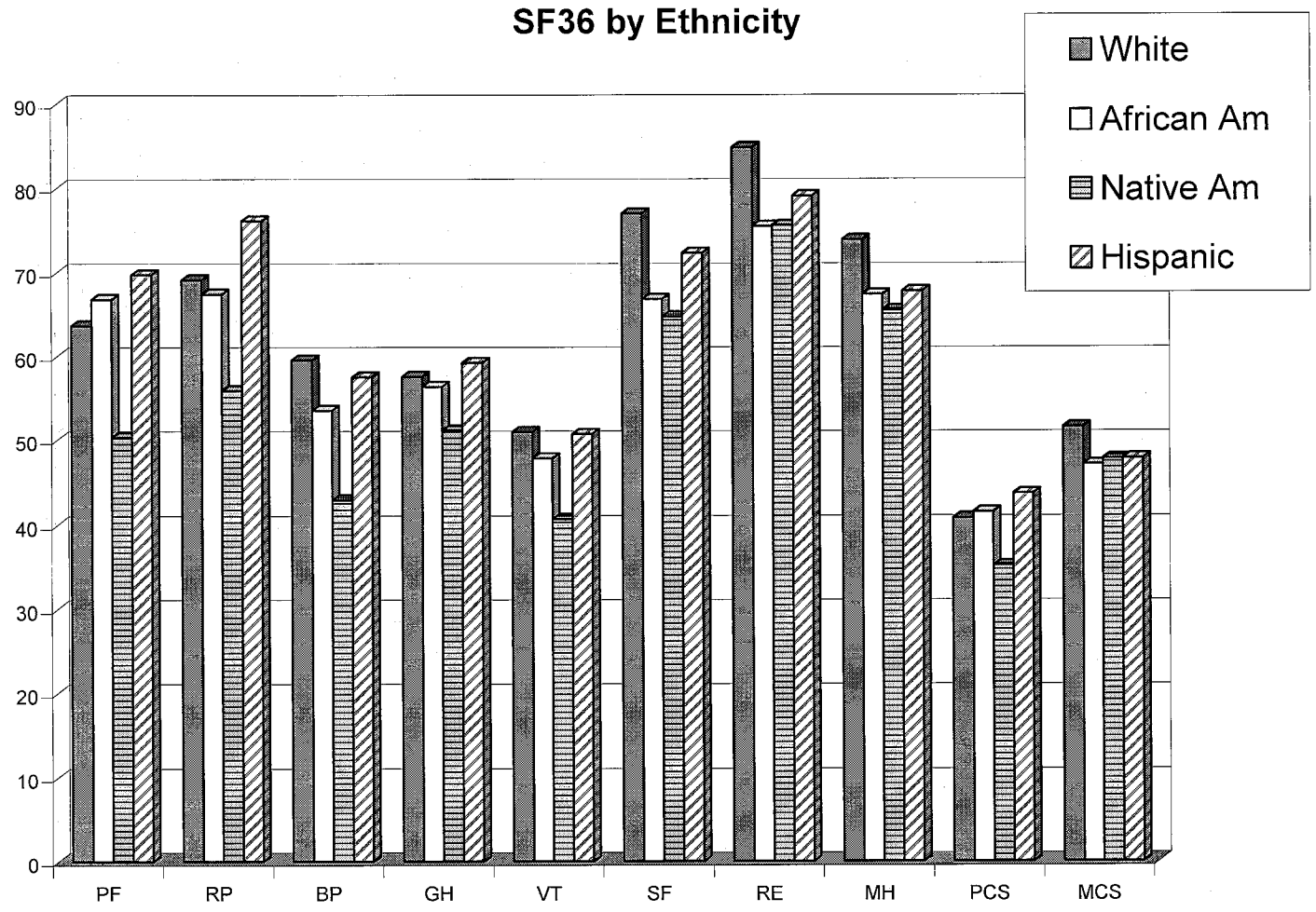


Figure 2.3 SF36 scores of participants in the Veterans Sleep Study, stratified by race and ethnicity.

Table 2.2 shows the correlations of the mental health composite (MCS) and Physical health composite (PCS) scales of the SF36 with the CIDI case probabilities. As expected there are strong correlations between the mental health scales of the SF36 and the probability of being judged a case using the CIDI scales. All CIDI scales are correlated with the MCS. The strength of the association is greatest for Major Depression and Generalized Anxiety. Correlations with the PCS are weaker. Because of the large sample size, nearly all correlations are statistically significant. Thus, the actual size of the correlation coefficient is more important than the p value in this context. The data for the detailed scales of the SF36 are shown in Appendix A, Tables A.10.a and A.10.b. The sign of the coefficients is negative because the scales are scored in different directions.

		Veterans SF36 Scales	
CIDI scale		Mental Health Composite (MCS)	Physical Health Composite (PCS)
Major Depression (prob. of case)	Rho P N	-0.52 <.0001 1723	-0.22 <.0001 1723
General Anxiety Disorder (case)	Rho P N	-0.45 <.0001 1701	-0.16 <.0001 1701
Specific Phobia (prob. of case)	Rho P N	-0.25 <.0001 1725	-0.11 <.0001 1725
Social Phobia (prob. of case)	Rho P N	-0.26 <.0001 1719	-0.11 <.0001 1719
Agoraphobia (prob. of case)	Rho P N	-0.23 <.0001 1719	-0.13 <.0001 1719
Panic Disorder (prob. of case)	Rho P N	-0.26 <.0001 1708	-0.09 .0003 1708
Alcohol Dependence (prob. of case)	Rho P N	-0.17 <.0001 1723	0.02 .36 1723
Drug Dependence (prob. of case)	Rho P N	-0.16 <.0001 1712	-0.04 .07 1712

Table 2.2. Correlation (Spearman's Rho) of SF36 composite scales with CIDI scales

Task 3:

Document the level of health care utilization at baseline interview and at one year follow-up associated with insomnia and RLS adjusting for comorbid health conditions.

Contributes to research goal:

- To document the level of health care utilization at baseline interview and at one year follow-up associated with insomnia and RLS adjusting for comorbid health conditions;

Because patients of the VA health care system often use health care providers outside of the VA in addition to VA providers, we obtained data both from the VA medical record and from patient interview.

The baseline utilization data were obtained from the Time 1 questionnaires and from medical record data that was obtained shortly thereafter.

Task 3.a Conduct interviews by mail with 1914 VA clients to determine health care utilization one year after baseline interview.

The one year follow-up interviews were completed in September, 2005. A total of 1248 follow-up surveys were returned to us, which is a 71% response rate. Tables 3.1 through 3.3 show the demographic characteristics of the Time 2 respondents. In addition, among the respondents to the Time 2 survey, 29 (2.3%) had reported at Time 1 that they were of Hispanic origin.

	Time 1: Number	Time 2: Number (% of Time 1)
Males		
Age < 41	85	31 (36)
Age 41-50	184	95 (52)
Age 51-60	282	203 (72)
Age 61-70	252	201 (80)
Age 71-80	298	225 (76)
Age > 80	311	262 (84)
Females		
Age < 51	185	103 (56)
Age > 50	164	128 (78)
Total	1761	1248 (71)

Table 3.1. Age and gender distribution of respondents to Time 2 survey in comparison to Time 1.

Primary Race/ Ethnicity	Time 1: Number	Time 2: Number (% of Time 1)
American Indian or Alaskan Native	14	10 (71)
Asian	5	3 (60)
Black or African American	144	63 (44)
White or Caucasian	1565	1119 (72)
No response	7	

Table 3.2. Distribution of Time 2 respondents by race in comparison to Time 1 .

Secondary Race / Ethnicity	Time 1: Number	Time 2: Number (% of Time 1)
American Indian or Alaskan Native	46	31 (67)
Asian	2	2 (100)
Black or African American	4	1 (25)
White or Caucasian	4	3 (75)
None reported	1705	

Table 3.3. Distribution of study members by second reported race in comparison to Time 1 .

Task 3.b Extract time 2 utilization data from 1914 electronic medical records.

Time 2 medical record data can be obtained after the one year anniversary of the study member's interview. We have obtained all of the Time 2 utilization data with one exception. Our plan includes obtaining refill data up to 6 months after the survey in order to include prescriptions which are refilled infrequently. The last of this data will not be available until March, 2006.

Task 3.c Data entry, cleaning, and analysis

Data entry and cleaning occur as data arrives in our office. Questionnaire data have been entered and cleaned. Data analysis must wait for the completion of medical record data collection.

Methods

Study members were asked at Time 1 and Time 2 interview about their use of health services in the month prior to interview. They were also asked if the health care event occurred at a VA or non VA facility. We also obtained medical record data from VAMC files for office visits, hospitalizations, inpatient and outpatient surgery, laboratory tests, radiology, and prescriptions. Prescription data was obtained only from VAMC records. Most patients fill their prescriptions through the VA pharmacy as VA drug cost are substantially cheaper than other pharmacies.

Our plan is to use the VA records as the best source of care provided by the VAMC. Because study members may also receive care from outside physicians, reported health care provided by non-VA sources will be combined with VA care. By combining this information, we hope to develop a fairly complete picture of the health care utilization of study members.

Results

We have begun the preliminary descriptive analysis of this data. Table 3.4 shows levels of utilization reported by study participants in the Time 1 questionnaire. Table 3.5 shows the corresponding data from the medical record. Tables A.11.a through A.12.b in Appendix A show this data in more detail. We speculate that the larger number of physician visits reported by patients results from a combination of visits to outside physicians and patient reporting of visits that actually occurred outside of the one month interval. In the patient data, all tests (including laboratory and radiology) are combined. In the medical record data, we are able to separate them. The number of diagnostic tests found in the medical record is large as each individual test (for example, in a panel of tests) is counted separately.

As these data are for a one month period, there are few hospitalizations. Female patients also reported 4 same day and 10 inpatient surgical procedures. Males reported 18 same day surgeries and 58 inpatient surgeries. We found a total of 4 surgical procedures (1 female, 3 males) in the medical record. Again, we speculate that the discrepancy results from a combination of patient over reporting and use of physicians outside the VA.

	Males		Females		All	
	Mean	SD	Mean	SD	Mean	SD
MD visits	2.16	2.05	2.22	1.95	2.17	2.03
Days hospitalized	0.18	1.44	0.30	2.56	0.20	1.72
Diagnostic tests	1.13	0.83	1.08	0.89	1.12	0.85

Table 3.4 Mean levels of health care utilization reported by study participants at Time 1 interview.

	Males		Females		All	
	Mean	SD	Mean	SD	Mean	SD
MD visits	1.65	1.61	2.53	3.51	1.82	2.16
Prescriptions	6.78	6.13	7.79	8.54	6.98	6.69
Diagnostic tests	19.92	24.02	16.25	23.87	19.20	24.03
Radiology procedures	0.15	.062	0.24	0.84	0.17	0.67
Days hospitalized	0.01	0.21	0.09	0.98	0.03	0.48

Table 3.5 Mean levels of health care utilization recorded in the medical record in the month prior to Time 1 interview.

We plan a separate journal article exploring the impact of RLS and insomnia on levels of health care utilization.

Task 4.

Assess the validity of the RLS questionnaire using interview by a trained clinician as the gold standard.

Contributes to research goal:
Assess the validity of the RLS questionnaire using interview by a trained clinician as the gold standard.

Task 4.a Recruit study members who are patients at the Akron CBOC and conduct clinical assessment.
Task 4.b Analyze data

Methods.

Patients who are participants in the main study and who obtain their primary care at the Akron CBOC are being recruited into the Validation substudy. For the Validation interview, the insomnia severity scale and the RLS questionnaire are administered by a registered nurse. Patients then meet with Dr. Margaret Panzner for a clinical interview. If a study member reports symptoms of RLS, Dr. Panzner make a clinical determination about RLS case status or determines that the symptoms result from an RLS mimic. For patients who are judged to be cases, Dr. Panzner classifies the disease as primary or secondary to some other health condition.

The planned data analysis included: 1) calculation of the sensitivity and specificity of the Time 1 interview and the Validation interview using the clinical interview as the gold standard for both comparisons; calculation of the associated 95% confidence intervals; and 3) calculation of the test-retest reliability of the RLS instrument from Time 1 to Validation interview using the Kappa statistic.

Results

Our sample size goal for this substudy is 82 study members. Sixty-eight study members have completed the protocol. Dr. Panzner is able to schedule a maximum of 2 patient interviews a week and data collection is continuing.

The following are preliminary analysis based on the data that have been collected at this time.

Table 1 shows the demographic characteristics of the current study members.

		Males		Females	
		Number	Percent	Number	Percent
Age Group	20's	0	0	0	0
	30's	2	3.3	1	14.3
	40's	4	6.6	1	14.3
	50's	14	23.0	3	42.7
	60's	16	26.2	1	14.3
	70's	12	19.7	0	0
	80's	13	21.3	1	14.3
	Total	61	100.0	7	100.0

Table 4.1. Demographic characteristics of study members

Table 4.2 shows the evaluation of the questionnaires using the available data.

	Sensitivity	95% CI	Specificity	95% CI
Time 1 Interview	0.73	0.59 – 0.87	0.81	0.67 – 0.95
Validation Interview	0.70	0.55 – 0.85	0.71	0.55 – 0.87

Table 4.2 Test characteristics of the RLS questionnaire at Time 1 and Validation interview.

Task 4.c Manuscript preparation

Manuscript preparation is awaiting the completion of data collection.

Task 5.

Assess the external validity of the Sleep Study sample with respect to the population of VA patients who have had a visit in the past year.

Contributes to research goal:

- To estimate the prevalence of Restless Legs Syndrome and insomnia.

Task 5.a Extract population data from electronic patient record system
Task 5.b Data analysis

These two tasks are complete.

Method.

We obtained datasets which contained a record for each primary care visit and for each new prescription for each patient who received outpatient care at the Cleveland VAMC for the fiscal year, October 1, 2003 to September 30, 2004. The data included: date of each primary care visit; date of each new prescription; and the drug class code. These data were merged with a dataset which contained patient age and gender. The data of participants in our RLS research was identified. This dataset was used for all of the analysis reported for Task 5.

Results

We compared: the age and gender distribution of the VA Sleep Study participants to all patients obtaining care at the Cleveland VAMC (Table 5.1) ; and compared the mean number of primary care visits (Table 5.2) and mean number of new prescriptions (Table 5.3) for the two patient groups. We also show the frequency distributions of number of primary care visits (Figure 5.1) and number of new prescriptions (Figure 5.2) for the two patient groups.

We do not present statistical tests for the data evaluated in this Task. Because of the extremely large sample size for the Cleveland VAMC Outpatient arm of the comparison, any statistical test is expected to find a statistically significant difference. Therefore, conclusions based on such tests would be meaningless.

		Cleveland VA Outpatient care		Sleep Study participants	
Males		Number	Percent	Number	Percent
Age Group	20's	515	0.8	16	1.1
	30's	1431	2.3	50	3.6
	40's	4082	6.6	154	11.0
	50's	12843	20.6	273	19.5
	60's	12263	19.7	250	17.9
	70's	19609	31.5	286	20.4
	80's	11556	18.6	370	26.5
	Total	62299	100.0	1399	100.0
Females					
Age Group	20's	191	8.2	25	7.3
	30's	348	15.0	42	12.2
	40's	594	25.5	101	29.5
	50's	516	22.2	79	23.0
	60's	204	8.8	40	11.7
	70's	136	5.8	16	4.7
	80's	338	14.5	40	11.7
	Total	2327	100.0	343	100.0

Table 5.1. Comparison of gender-age distribution of study members to Cleveland VAMC outpatient population, fiscal year, October, 2003 to September, 2004.

Gender	Age Group	Patients in Sleep Study Mean n. visits (s.d., n)	Cleveland VAMC population Mean n. visits (s.d., n)
Females	20	4.64 (2.84, 25)	2.90 (3.03, 191)
	30	3.71 (2.58, 42)	3.03 (2.84, 348)
	40	5.73 (4.14, 101)	3.39 (2.86, 594)
	50	5.23 (3.65, 79)	3.79 (2.90, 516)
	60	4.03 (2.52, 40)	3.99 (3.24, 204)
	70	3.38 (1.82, 16)	3.38 (3.04, 136)
	80	4.48 (3.49, 40)	2.99 (2.31, 338)
	Total	4.83 (3.52, 343)	3.38 (2.87, 2327)
Males	20	3.00 (2.39, 16)	2.02 (1.57, 515)
	30	3.14 (2.11, 50)	2.30 (1.94, 1431)
	40	4.01 (3.02, 154)	2.79 (2.31, 4082)
	50	4.73 (6.60, 273)	3.38 (2.88, 12843)
	60	4.30 (3.48, 250)	3.40 (2.79, 12263)
	70	3.93 (3.43, 286)	3.17 (2.50, 19609)
	80	3.72 (2.83, 370)	3.23 (2.55, 11556)
	Total	4.06 (4.07, 1399)	3.21 (2.63, 62299)

Table 5.2. Mean number of primary care visits (unadjusted) stratified by gender and age.

Gender	Age Group	Patients in Sleep Study Mean n. Rx. (s.d., n)	Cleveland VAMC population Mean n. Rx. (s.d., n)
Females	20	7.36 (6.78, 25)	5.17 (6.69, 191)
	30	11.98 (10.31, 42)	8.18 (9.03, 348)
	40	20.71 (21.02, 101)	14.76 (17.56, 594)
	50	19.06 (16.60, 79)	17.47 (18.70, 516)
	60	16.88 (10.24, 40)	16.68 (17.22, 204)
	70	13.13 (10.83, 16)	14.93 (15.04, 136)
	80	13.65 (9.81, 40)	12.11 (10.98, 338)
	Total	16.66 (15.90, 343)	13.38 (15.60, 2327)
Males	20	4.63 (5.15, 16)	3.89 (5.73, 515)
	30	7.02 (7.91, 50)	6.65 (9.63, 1431)
	40	14.85 (14.24, 154)	12.30 (15.49, 4082)
	50	17.04 (15.06, 273)	14.31 (14.98, 12843)
	60	14.64 (12.49, 250)	12.65 (12.92, 12263)
	70	12.52 (8.62, 286)	11.59 (10.26, 19609)
	80	11.63 (8.49, 370)	11.50 (9.52, 11556)
	Total	13.52 (11.71, 1399)	12.21 (12.23, 62299)

Table 5.3. Mean number of new prescriptions stratified by gender and age.

Figure 5.1. Primary Care Visits

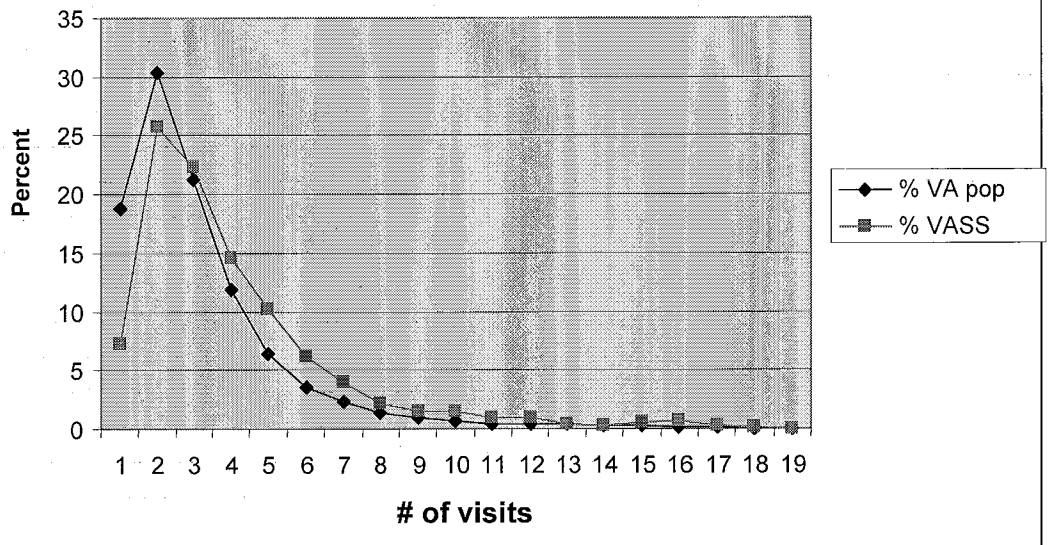
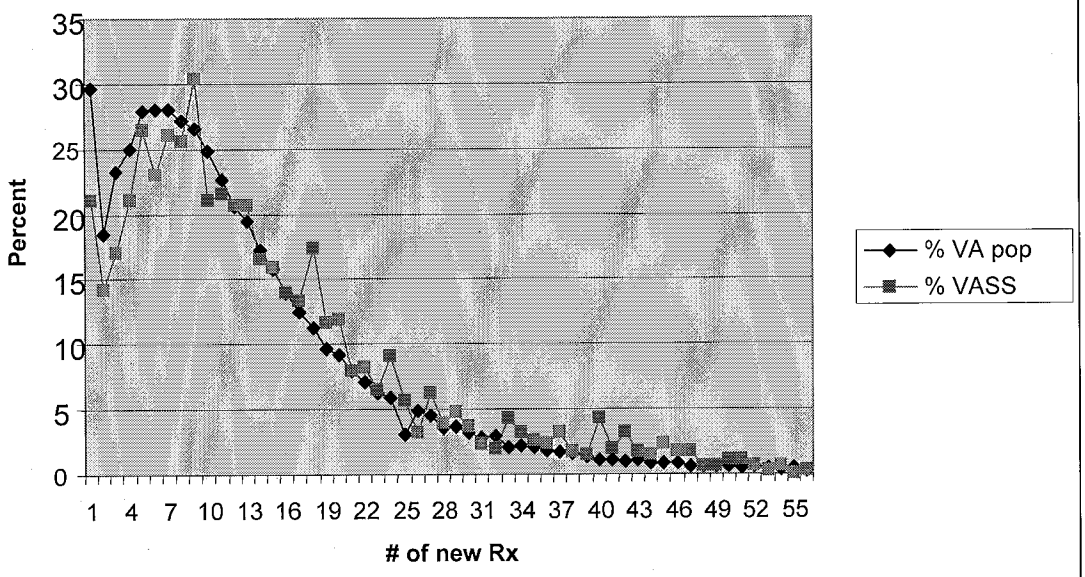


Figure 5.2. Number of New Prescriptions



The gender- age distributions of the Veterans Sleep study sample and the Cleveland VAMC outpatient population are only roughly similar. We did not expect the gender-age distribution of the sample to exactly represent the population. The differences result from the sampling scheme for the Sleep Study sample which was designed to obtain precise estimates of RLS and insomnia prevalence in gender-age strata rather than to directly represent the demographics of the background population.

Tables 5.2 and 5.3 suggest that the participant in the VA Sleep Study are somewhat sicker than the background population. Sleep Study participants had 0.95 more office visits (4.17 visits versus 3.22 visits) and 1.74 more new prescriptions (13.99 versus 12.25) than the overall population. This is expected because the study members were recruited at the time of a primary care visit. Using this sampling scheme, persons who make more office visits have a higher probability of being sampled. Lee and colleagues documented the effect of this sampling approach in a VA sample and concluded that that such a sample represents the subgroup of patients who have 4 or more office visits of any type during a year.(12) These authors found that patients selected at a primary care office visit had 0.8 more primary care visits in a year. We plan additional analysis following the model of Lee and colleagues to determine to what extent their conclusions apply to the Sleep Study sample or alternatively, what subgroup of the VA population is represented by the Sleep Study sample.

Figures 5.1 and 5.2 indicate that the utilization characteristics of the Sleep Study sample, like the background population, are skewed to the right. The overall frequency distributions of the study sample are shifted to the right of the background population.

Task 5.c **Manuscript preparation.** This information will be incorporated in the manuscript in preparation for *Task 1.* The paper by Lee and colleagues contains an important discussion of the utility of such visit based samples. Points from their discussion will be included in the

discussion of the external validity and conclusions which can be drawn from the sample included in this research.

Task 6

Conduct a pilot study of an aerobic exercise intervention to improve sleep quality among RLS patients by moderating their RLS symptoms.

Identify RLS cases, confirm diagnosis and recruit up to 30 study members. Hire and train staff. (Months 25 – 27)
Compliance trial. (Month 28)
Conduct 3 month crossover study. 3 month intervention and 3 month control condition. (Month 29-34)
Analyze data and prepare report. (Month 35-36)

Human Subject approval of the project by the Department of Defense IRB was received in July, 2005. At that time, hiring and training personnel started.

The study protocol calls for two arms of the study, one carried out through the Community Based Outpatient Center (CBOC) located in Akron, Ohio and one through the CBOC located in Youngstown, Ohio. Eligible study members must be definite or probable RLS cases, and meet a series of other eligibility criteria.

Intake of study members began at the Akron CBOC in December, 2005. Arrangements had been made with an exercise facility on the south side of the city and patients who lived generally south of the city were invited. Forty-seven patients were invited to the intake meeting. Reminder calls were made to all. At that time, 12 patients indicated that they planned to attend the meeting. Six patients actually attended the meeting. Of these attendees, 2 met all of the eligibility criteria for the study. Neither of these 2 patients returned for either of the subsequent compliance meetings.

After this disappointing result, we have decided to move the Akron arm of the study to an exercise facility located in the northwest part of the city and invite patients from geographic areas to the north and west of the city. We are waiting for IRB approval of this change to the protocol.

An intake meeting is scheduled for the Youngstown CBOC for March 14, 2006. Fifty-three potential study members have been identified from questionnaire responses and their medical records have been reviewed for a preliminary test of eligibility. We learned from our failed attempt in Akron that we need to review the medical records more stringently in advance of the intake meeting. Thus, a larger proportion of invitees should be eligible for the study. We hope that being past the holiday season and approaching spring may improve attendance. As always with pilot studies both success and failure are learning experiences.

KEY RESEARCH ACCOMPLISHMENTS

- Recruited and interviewed 1761 study members.
- Extracted Time 1 and Time 2 (prescription data still outstanding) medical record data for 1761 study members.
- Cleaned time 1 datasets and prepared working data files.
- Mailed 1761 follow-up questionnaires; obtained 71% response to follow-up survey. Cleaned survey datasets.
- Completed description of study participants.
- Calculated preliminary estimates of the prevalence of RLS, insomnia, and daytime sleepiness.
- Calculated preliminary estimates of Attributable Risk % of factors contributing to insomnia and daytime sleepiness.
- Obtained utilization data on background population and assessed comparability of study sample to background population.
- Complete data for 68 participants in the Validation Substudy. Preliminary calculation of sensitivity and specificity of diagnostic instrument.

REPORTABLE OUTCOMES

Poster presented at the meeting of the Associated Professional Sleep Societies (APSS) meeting, Denver, June, 2005. Related abstract published in a special issue of the Journal, *Sleep* 2005; 26:A276.

Paper presented at the annual meeting of the Society for Epidemiologic Research, Toronto, Ontario, Canada, June, 2005. Related abstract published in a special issue of *the American Journal of Epidemiology* 2005; 161(S1):A90.

Poster presented at the Case Western Reserve University Research Showcase; April, 2005; Cleveland, OH. Ober SK, Bourguet CC, and Baughman KR. Insomnia and Daytime Sleepiness: Risk attributable to RLS, BMI, smoking, and alcohol in a VA outpatient population.

CONCLUSIONS

Using number of primary care visits and new prescriptions as a criteria, the participants in the Veterans Sleep Study are comparable to a subgroup of Veterans who have more than one office visit each year. In a comparison of SF36 profiles, the Sleep Study participants show an overall health related quality of life profile similar to the US population as a whole and to participants in the Veterans Health Study. Sleep Study participants report, however, better health related quality of life than Veterans Health Study participants and poorer health related quality of life than the US referent sample.

Based on preliminary data, the Johns Hopkins Restless Legs Syndrome diagnostic telephone interview has a 73% sensitivity and 81% specificity using an interview by a physician trained in the diagnosis of RLS as the gold standard.

Restless Legs Syndrome, Insomnia, and Daytime Sleepiness are common complaints among primary care patients seen at VA outpatient clinics. In this patient population at least 20% of RLS may be secondary to other health conditions. RLS, obesity, alcohol dependence, and gender are significant risk factors for insomnia. Insomnia, in turn, is a significant risk factor for daytime sleepiness. RLS is a significant risk factor for daytime sleepiness, even after controlling for insomnia. Because of the high prevalence of obesity, RLS, and insomnia in this patient population, the Attributable Risk associated with these factors is substantial.

Despite the impact of RLS on insomnia and daytime sleepiness, few patients are diagnosed with RLS (4%), insomnia (29%) or daytime sleepiness (26%) by their physicians.

These conclusions are only descriptive and are based on preliminary analysis of the data.

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APPENDICES

A. Detailed tables

B. Abstracts presented at scientific meetings.

Appendix A – Detailed Tables

Table A.1: Demographic Characteristics of Sleep Study Sample.

Table A.2. Prevalence of RLS, Insomnia, and Daytime Sleepiness by Gender and Age.

Table A.3. Conditions capable of causing RLS symptoms (secondary RLS) from medical record.

Table A.4 Diagnosis of RLS at the VA (either on the current problems list or diagnosed in the past but no longer on problems list).

Table A.5. Persons ever diagnosed with a sleep problem at the VA stratified by Insomnia Severity Scale scores.

Table A.6. Persons ever diagnosed with a sleep problem at the VA stratified by Epworth Sleepiness Scale scores.

Table A.7. Proportion of insomnia and excessive daytime sleepiness attributable to RLS and other risk factors.

Table A.8 Proportion of Sleep Study members meeting the CIDI criteria for the DSM-IV diagnosis of mental health and substance disorders, stratified by gender and age.

Table A.9 Scores on the Veterans SF36 scale stratified by age and gender.

Table A.10.a Spearman Correlations between probability of DSM-IV diagnosis assigned by CIDI score and SF36 mental health scales.

Table A.10.b Spearman Correlations between probability of DSM-IV diagnosis assigned by CIDI score and SF36 physical health scales.

Table A.11.a Self-Reported Utilization by Age and Gender.

Table A.11.b Self-Reported Utilization by Ethnicity and Gender.

Table A.12.a Medical Record Report of Utilization by Age and Gender.

Table A.12.b Medical Record Report of Utilization by Ethnicity and Gender.

Table A.1: Demographic Characteristics ofSleep Study Sample

	Women	Men	All
	% (n)	% (n)	% (n)
Age 20-29	7.7 (27)	1.4 (20)	2.7 (47)
Age 30-39	12.9 (45)	3.8 (53)	5.6 (98)
Age 40-49	30.1 (105)	11.8 (167)	15.5 (272)
Age 50-59	22.4 (78)	20.3 (287)	20.7 (365)
Age 60-69	11.2 (39)	17.9 (252)	16.5 (291)
Age 70-79	5.4 (19)	20.0 (283)	17.2 (302)
Age 80+	10.3 (36)	24.8 (350)	21.9 (386)
Total	100 (349)	100 (1412)	100 (1761)
Hispanic	2.6 (9)	2.3 (32)	2.4 (41)
White	74.3 (252)	91.4 (1270)	88.1 (1522)
African American	17.7 (60)	5.6 (78)	8.0 (138)
Native American	4.7 (16)	2.5 (35)	3.0 (51)
Asian American	1.2 (4)	.2 (3)	.4 (7)
Other	2.1 (7)	.2 (3)	.6 (10)
Total	100 (339)	100 (1389)	100 (1728)
BMI < 25	26.3 (89)	17.9 (250)	19.6 (339)
BMI 25-29	29.8 (101)	41.6 (580)	39.3 (681)
BMI > 29	44.0 (149)	40.5 (564)	41.14 (713)
Total	100 (339)	100 (1394)	100 (1733)
Grade School	0 (0)	3.3 (46)	2.6 (46)
Some High School	2.9 (10)	12.9 (180)	10.9 (190)
High School graduate	31.8 (110)	43.2 (604)	40.9 (714)
Some College	43.4 (150)	26.9 (376)	30.2 (526)
College graduate	18.8 (65)	10.3 (144)	12.0 (209)
Graduate School	3.2 (11)	3.4 (48)	3.4 (59)
Total	100 (346)	100 (1398)	100 (1744)
Currently Smokes	31.4 (109)	19.7 (275)	22.0 (384)

Table A.2. Prevalence of RLS, Insomnia, and Daytime Sleepiness by Gender and Age

	Women	Men	All
RLS definite case (4 symptoms at least 2-4 days per month) *			
Age 20-29	.15 (CI: . , .), 4/26	.15 (CI: . , .), 3/20	.15 (CI: . , .), 7/46
Age 30-39	.34 (CI: . , .), 15/44	.21 (CI: . , .), 11/53	.27 (CI: . , .), 26/97
Age 40-49	.34 (CI: . , .), 36/105	.22 (CI: . , .), 37/167	.27 (CI: . , .), 73/272
Age 50-59	.28 (CI: . , .), 21/75	.27 (CI: . , .), 76/281	.27 (CI: . , .), 97/356
Age 60-69	.30 (CI: . , .), 11/37	.20 (CI: . , .), 49/246	.21 (CI: . , .), 60/283
Age 70-79	.17 (CI: . , .), 3/18	.13 (CI: . , .), 37/278	.14 (CI: . , .), 40/296
Age 80+	.18 (CI: . , .), 6/34	.11 (CI: . , .), 37/337	.12 (CI: . , .), 43/371
For all ages	.28 (CI: . , .), 96/339	.18 (CI: . , .), 250/1382	.20 (CI: . , .), 346/1721
RLS definite and probable case (4 sx) and (3 Sx's at least 2-4 days per month or leg feelings or urge to move +walkrelief+2-4 days per month)			
Age 20-29	.46 (CI: . , .), 12/26	.40 (CI: . , .), 8/20	.43 (CI: . , .), 20/46
Age 30-39	.50 (CI: . , .), 22/44	.49 (CI: . , .), 26/53	.49 (CI: . , .), 48/97
Age 40-49	.54 (CI: . , .), 57/105	.50 (CI: . , .), 84/167	.52 (CI: . , .), 141/272
Age 50-59	.51 (CI: . , .), 38/75	.53 (CI: . , .), 149/281	.53 (CI: . , .), 187/356
Age 60-69	.46 (CI: . , .), 17/37	.39 (CI: . , .), 97/246	.40 (CI: . , .), 114/283
Age 70-79	.33 (CI: . , .), 6/18	.31 (CI: . , .), 87/278	.31 (CI: . , .), 93/296
Age 80+	.35 (CI: . , .), 12/34	.27 (CI: . , .), 92/337	.28 (CI: . , .), 104/371
For all ages	.48 (CI: . , .), 64/339	.39 (CI: . , .), 543/1382	.41 (CI: . , .), 707/1721
* CI's are not shown because the prevalence estimates are subject to change based on new data from the Validation Substudy.			

	Women	Men	All
	Prev. (95% CI), N	Prev. (95% CI), N	Prev. (95% CI), N
Moderate Insomnia			
Age 20-29	.15 (CI: .05, .33), 27	.15 (CI: .05, .37), 20	.15 (CI: .07, .28), 47
Age 30-39	.31 (CI: .18, .45), 45	.11 (CI: .05, .23), 53	.20 (CI: .12, .28), 98
Age 40-49	.29 (CI: .20, .37),105	.19 (CI: .13, .25), 67	.23 (CI: .18, .28), 272
Age 50-59	.22 (CI: .13, .31), 78	.21 (CI: .16, .25),287	.21 (CI: .17, .25), 365
Age 60-69	.10 (CI: .04, .24), 39	.09 (CI: .06, .13),252	.09 (CI: .06, .13), 291
Age 70-79	.11 (CI: .02, .33), 19	.07 (CI: .04, .10),283	.07 (CI: .04, .10), 302
Age 80+	.11 (CI: .04, .26), 36	.03 (CI: .02, .05),350	.04 (CI: .02, .06), 386
For all ages	.21 (CI: .17, .26),349	.11 (CI: .09, .13), 1412	.13 (CI: .11, .15), 1761
Severe Insomnia			
Age 20-29	.00, 27	.00, 20	.00, 47
Age 30-39	.09 (CI: .03, .21), 45	.06 (CI: .01, .16), 53	.07 (CI: .03, .14), 98
Age 40-49	.07 (CI: .03, .13),105	.07 (CI: .03, .10),167	.07 (CI: .04, .10), 272
Age 50-59	.09 (CI: .04, .18), 78	.06 (CI: .03, .09),287	.07 (CI: .04, .09), 365
Age 60-69	.03 (CI: .00, .15), 39	.03 (CI: .01, .06),252	.03 (CI: .01, .05), 291
Age 70-79	.00, 19	.01 (CI: .00, .03),283	.01 (CI: .00, .03), 302
Age 80+	.00, 36	.003 (CI: .00, 02), 350	.003 (CI: .00, .02), 386
For all ages	.05 (CI: .03, .08),349	.03 (CI: .02, .04), 1412	.03 (CI: .03, .04), 1761

Table A.2. Continued

	Women	Men	All
	Prev. (95% CI), N	Prev. (95% CI), N	Prev. (95% CI), N
Moderate Daytime Sleepiness			
Age 20-29	.30 (CI: .16, .49), 27	.25 (CI: .11, .47), 20	.28 (CI: .15, .40), 47
Age 30-39	.18 (CI: .09, .32), 45	.21 (CI: .10, .32), 53	.19 (CI: .12, .27), 98
Age 40-49	.24 (CI: .16, .32), 105	.20 (CI: .14, .26),167	.22 (CI: .17, .27), 272
Age 50-59	.18 (CI: .09, .26), 78	.22 (CI: .17, .27),287	.21 (CI: .17, .26), 365
Age 60-69	.23 (CI: .13, .39), 39	.17 (CI: .12, .22),252	.18 (CI: .13, .22), 291
Age 70-79	.16 (CI: .05, .39), 19	.13 (CI: .09, .17),283	.14 (CI: .10, .17), 302
Age 80+	.17 (CI: .08, .32), 36	.14 (CI: .10, .17),349	.14 (CI: .11, .17), 385
For all ages	.21 (CI: .17, .25), 349	.17 (CI: .15, .19), 1411	.18 (CI: .16, .20), 1760
Severe Daytime Sleepiness			
Age 20-29	.00, 27	.00, 20	.00, 47
Age 30-39	.04 (CI: .00, .16), 45	.06 (CI: .01, .16), 53	.05 (CI: .02, .12), 98
Age 40-49	.11 (CI: .05, .16), 105	.12 (CI: .07, .17),167	.11 (CI: .08, .15), 272
Age 50-59	.12 (CI: .06, .21), 78	.12 (CI: .08, .15),287	.12 (CI: .08, .15), 365
Age 60-69	.00, 39	.08 (CI: .05, .12),252	.07 (CI: .04, .10), 291
Age 70-79	.00, 19	.06 (CI: .03, .08),283	.05 (CI: .03, .08), 302
Age 80+	.03 (CI: .00, .16), 36	.03 (CI: .01, .05),349	.03 (CI: .01, .05), 385
For all ages	.07 (CI: .04, .09), 349	.07 (CI: .06, .09), 1411	.07 (CI: .06, .08), 1760

Table A.3 Conditions capable of causing RLS symptoms (secondary RLS) from medical record and patient report.

	RLS definite		RLS probable and definite	
	Number	%	Number	%
Any anemia	40	12	85	12
Any kidney disease	11	3	22	3
Any movement disorder	1	0.003	2	0.003
Any neuropathy	73	21	161	23
SSRI use	78	23	156	22
Total RLS	346		707	

Table A.4. Diagnosis of RLS at the VA (either on the current problems list or diagnosed in the past but no longer on problems list)

	Definite RLS cases	Probable RLS cases
Diagnosis at VA		
No	331 (96%)	685 (97%)
Yes	15 (4%)	22 (3%)
Total	346 (100%)	707 (100%)

Table A.5. Persons ever diagnosed with a sleep problem at the VA stratified by Insomnia Severity Scale scores

	Sleep Study Diagnosis	
Diagnosis of sleep problem by VAMC	Moderate Insomnia	Severe Insomnia
No	160 (70%)	45 (74%)
Yes	69 (30%)	16 (26%)
Total	229	61

Table A.6. Persons ever diagnosed with a sleep problem at the VA stratified by Epworth Sleepiness Scale scores

	Sleep Study Diagnosis	
Diagnosis of sleep problem by VAMC	Severe Daytime Sleepiness	Moderate Daytime Sleepiness
No	81 (64%)	245 (78%)
Yes	46 (36%)	71 (22%)
Total	127	316

Table A.7. Proportion of insomnia and excessive daytime sleepiness attributable to RLS and other risk factors.

	Outcome: Insomnia		Outcome: Daytime Sleepiness	
	Odds Ratios	Attributable Risk %	Odds Ratios	Attributable Risk %
Risk factor				
Insomnia			3.17***	26.71
Frequent RLS case	2.90***	21.53	1.55**	7.30
Gender	1.61**(female),	10.67	1.17 (male),	11.99
Age 20-29	2.18	2.97	1.81	2.06
Age 30-39	4.38***	16.09	1.12	.68
Age 40-49	5.05***	38.93	1.74*	10.41
Age 50-59	5.66***	49.24	1.76**	13.61
Age 60-69	2.42**	19.02	1.37	5.81
Age 70-79	1.78	11.81	1.00	-0.03
Age 80+	Ref		Ref	
BMI < 25	Ref		Ref	
BMI 25-29	1.07	2.75	.97	-1.39
BMI > 29	1.88**	26.65	1.34	12.41
Alcohol Dependence	2.31**	4.10	.87	-.44
Currently Smokes	1.29	6.05	.91	-2.01

* p<.05
** p< .01
***p<.001

Table A.8. Portion of Sleep Study members meeting CIDI criteria for the DSM-IV diagnosis of mental health and substance disorders, stratified by gender and age.

	Women	Men	All
Major Depression			
Age 20-29	.44 (CI: .26, .63), 12/27	.32 (CI: .11, .52), 6/19	.39 (CI: .25, .53), 18/46
Age 30-39	.41 (CI: .26, .55), 18/44	.23 (CI: .11, .34), 12/53	.31 (CI: .22, .40), 30/97
Age 40-49	.42 (CI: .33, .52), 44/104	.40 (CI: .33, .47), 66/165	.41 (CI: .35, .47), 110/269
Age 50-59	.38 (CI: .28, .49), 30/78	.31 (CI: .26, .37), 90/286	.33 (CI: .28, .38), 120/364
Age 60-69	.15 (CI: .04, .27), 6/39	.12 (CI: .08, .16), 31/250	.13 (CI: .09, .17), 37/289
Age 70-79	.00, 0/19	.06 (CI: .03, .08), 16/282	.05 (CI: .03, .08), 16/301
Age 80+	.11 (CI: .01, .21), 4/36	.05 (CI: .03, .07), 17/347	.05 (CI: .03, .08), 21/383
For all ages	.33 (CI: .28, .38), 114/347*	.17 (CI: .15, .19), 238/1402*	.20 (CI: .18, .22), 352/1749*
Generalized anxiety disorder			
Age 20-29	.22 (CI: .07, .38), 6/27	.00, 0/19	.13 (CI: .03, .23), 6/46
Age 30-39	.26 (CI: .13, .39), 11/42	.17 (CI: .07, .28), 9/52	.21 (CI: .13, .30), 20/94
Age 40-49	.28 (CI: .19, .37), 28/99	.23 (CI: .16, .29), 37/164	.25 (CI: .19, .30), 65/263
Age 50-59	.19 (CI: .10, .28), 15/78	.18 (CI: .13, .22), 49/280	.18 (CI: .14, .22,), 64/358
Age 60-69	.08 (CI: .00, .17), 3/37	.08 (CI: .05, .12), 20/245	.08 (CI: .05, .11), 23/282
Age 70-79	.05 (CI: .00, .15), 1/19	.04 (CI: .02, .06), 11/279	.04 (CI: .02, .06), 12/298
Age 80+	.03 (CI: .00, .08), 1/36	.03 (CI: .01, .05), 10/341	.03 (CI: .01, .05), 11/377
For all ages	.19 (CI: .15, .23), 65/338	.10 (CI: .08, .11), 136/1380	.12 (CI: .10, .13), 201/1718
Specific phobia			
Age 20-29	.11 (CI: .00, .23), 3/27	.37 (CI: .15, .59), 7/19	.22 (CI: .10, .34), 10/46
Age 30-39	.20 (CI: .09, .32), 9/44	.19 (CI: .09, .30), 10/52	.20 (CI: .12, .28), 19/96
Age 40-49	.33 (CI: .24, .42), 34/104	.25 (CI: .18, .32), 41/164	.28 (CI: .23, .33), 75/268
Age 50-59	.28 (CI: .18, .38), 22/78	.19 (CI: .15, .24), 55/285	.21 (CI: .17, .25), 77/363
Age 60-69	.21 (CI: .08, .34), 8/38	.11 (CI: .07, .15), 27/250	.12 (CI: .08, .16), 35/288
Age 70-79	.00, 0/19	.06 (CI: .03, .08), 16/282	.05 (CI: .03, .08), 16/301
Age 80+	.08 (CI: .00, .17), 3/36	.04 (CI: .02, .06), 14/346	.04 (CI: .02, .07), 17/382
For all ages	.23 (CI: .18, .27), 79/346	.12 (CI: .10, .14), 170/1398	.14 (CI: .13, .16), 249/1744
Social phobia			
Age 20-29	.07 (CI: .00, .17), 2/27	.00, 0/19	.04 (CI: .00, .10), 2/46
Age 30-39	.09 (CI: .01, .18), 4/44	.06 (CI: .00, .12), 3/51	.07 (CI: .02, .13), 7/95
Age 40-49	.20 (CI: .12, .28), 21/104	.12 (CI: .07, .17), 19/163	.15 (CI: .11, .19), 40/267
Age 50-59	.13 (CI: .05, .20), 10/78	.09 (CI: .06, .12), 25/284	.10 (CI: .07, .13), 35/362
Age 60-69	.05 (CI: .00, .12), 2/38	.04 (CI: .02, .06), 10/250	.04 (CI: .02, .06), 12/288
Age 70-79	.05 (CI: .00, .15), 1/19	.02 (CI: .00, .03), 5/280	.02 (CI: .00, .04), 6/299
Age 80+	.05 (CI: .00, .08), 1/36	.02 (CI: .01, .04), 7/345	.02 (CI: .01, .04), 8/381
For all ages	.12 (CI: .08, .15), 41/346	.05 (CI: .04, .06), 69/1392	.06 (CI: .05, .07), 110/1738
Agoraphobia			
Age 20-29	.15 (CI: .01, .28), 4/27	.00, 0/19	.09 (CI: .01, .17), 4/46
Age 30-39	.02 (CI: .00, .07), 1/44	.02 (CI: .00, .06), 1/52	.02 (CI: .00, .05), 2/96
Age 40-49	.15 (CI: .08, .22), 16/104	.09 (CI: .05, .14), 15/163	.12 (CI: .08, .15), 31/267
Age 50-59	.05 (CI: .00, .10), 4/78	.08 (CI: .05, .11), 22/284	.07 (CI: .05, .10), 26/362
Age 60-69	.05 (CI: .00, .12), 2/38	.02 (CI: .00, .03), 4/249	.02 (CI: .00, .04), 6/287
Age 70-79	.00, 0/19	.00, 0/281	.00, 0/300

	Women	Men	All
Age 80+	.03 (CI: .00, .08), 1/35	.01 (CI: .00, .03), 5/345	.02 (CI: .00, .03), 6/380
For all ages	.08 (CI: .05, .11), 28/345	.03 (CI: .02, .04), 47/1393	.04 (CI: .03, .05), 75/1738
Panic Attack			
Age 20-29	.19 (CI: .04, .34), 5/26	.03 (CI: .00, .32), 3/19	.18 (CI: .07, .29), 8/45
Age 30-39	.20 (CI: .09, .32), 9/44	.14 (CI: .04 .23), 7/51	.17 (CI: .09, .24), 16/95
Age 40-49	.18 (CI: .11, .26), 19/103	.13 (CI: .08, .18), 21/162	.15 (CI: .11, .19), 40/265
Age 50-59	.11 (CI: .04, .17), 8/76	.09 (CI: .06, .12), 25/284	.09 (CI: .06, .12), 33/360
Age 60-69	.05 (CI: .00, .12), 2/39	.02 (CI: .00, .04), 5/250	.02 (CI: .01, .04), 7/289
Age 70-79	.00, 0/19	.01 (CI: .00, .02), 3/281	.01 (CI: .00, .02), 3/300
Age 80+	.00, 0/36	.00, 0/344	.00, 0/380
For all ages	.12 (CI: .09, .16), 43/343	.05 (CI: .03, .06), 64/1391	.06 (CI: .05, .07), 107/1734
Alcohol Dependence			
Age 20-29	.04 (CI: .00, .11), 1/27	.05 (CI: .00, .15), 1/19	.04 (CI: .00, .10), 2/46
Age 30-39	.09 (CI: .01, .18), 4/44	.08 (CI: .00, .15), 4/52	.08 (CI: .03, .14), 8/96
Age 40-49	.06 (CI: .01, .10), 6/104	.09 (CI: .05, .14), 15/163	.08 (CI: .05, .11), 21/267
Age 50-59	.00, 0/78	.07 (CI: .04, .10), 19/285	.05 (CI: .03, .08), 19/363
Age 60-69	.00, 0/39	.02 (CI: .00, .03), 4/248	.01 (CI: .00, .03), 4/287
Age 70-79	.00, 0/19	.004 (CI: .00, .01), 1/282	.003 (CI: .00, .01), 1/301
Age 80+	.00, 0/36	.00, 0/347	.00, 0/383
For all ages	.03 (CI: .01, .05), 11/349	.03 (CI: .02, .04), 44/1396	.03 (CI: .02, .04), 55/1743
Drug Dependence			
Age 20-29	.00, 0/27	.05 (CI: .00, .15), 1/19	.02, (CI: .00, .06), 1/46
Age 30-39	.02 (CI: .00, .07), 1/44	.02 (CI: .00, .06), 1/52	.02 (CI: .00, .05), 2/96
Age 40-49	.05 (CI: .01, .09), 5/103	.04 (CI: .01, .07), 7/164	.04 (CI: .02, .07), 12/267
Age 50-59	.03 (CI: .00, .06), 2/78	.01 (CI: .00, .03), 4/280	.02 (CI: .00, .03), 6/358
Age 60-69	.00, 0/39	.00, 0/248	.00, 0/287
Age 70-79	.00, 0/19	.00, 0/281	.00, 0/300
Age 80+	.00, 0/36	.003 (CI: .00, .01), 1/342	.003 (CI: .00, .01), 1/378
For all ages	.02 (CI: .01, .04), 8/346	.01 (CI: .00, .02), 14/1386	.01 (CI: .01, .02), 22/1732

* The total number of respondents differs because some respondent chose not to respond to some sets of diagnostic questions.

Table A.9 Scores on the Veterans SF36 scale stratified by age and gender.

	Women	Men	All
Physical Functioning (PF)			
Age 20-29	76.7, 25.5 (27)	88.5, 14.9 (20)	81.7, 22.2 (47)
Age 30-39	74.1, 25.9 (44)	72.4, 27.4 (52)	73.2, 26.6 (96)
Age 40-49	58.7, 31.9 (105)	65.4, 30.9 (167)	62.8, 31.4 (272)
Age 50-59	51.7, 30.7 (77)	59.3, 29.5 (286)	57.7, 29.9 (363)
Age 60-69	60.9, 33.2 (39)	65.4, 27.4 (250)	64.8, 28.2 (289)
Age 70-79	56.7, 24.6 (19)	67.9, 25.3 (283)	67.2, 25.3 (302)
Age 80+	52.9, 26.4 (36)	64.8, 23.8 (349)	63.7, 24.2 (385)
For all ages	60.0, 30.6 (347)	65.1, 27.2 (1407)	64.1, 27.9 (1754)
Role Physical (RP)			
Age 20-29	77.1, 27.2 (27)	83.4, 23.7 (20)	79.8, 25.7 (47)
Age 30-39	69.3, 29.1 (44)	72.2, 34.7 (53)	70.9, 32.2 (97)
Age 40-49	60.8, 33.5 (105)	65.8, 33.2 (167)	63.9, 33.3 (272)
Age 50-59	60.0, 33.4 (77)	62.1, 34.1 (285)	61.6, 33.9 (362)
Age 60-69	71.2, 32.8 (39)	69.1, 31.5 (251)	69.4, 31.6 (290)
Age 70-79	70.4, 27.5 (19)	75.0, 28.0 (281)	74.7, 28.0 (300)
Age 80+	70.5, 26.2 (36)	73.5, 27.8 (349)	73.3, 27.6 (385)
For all ages	65.6, 31.7 (347)	69.9, 31.1 (1406)	69.1, 31.3 (1753)
Bodily Pain (BP)			
Age 20-29	63.0, 25.1 (27)	62.9, 31.8 (20)	63.0, 27.8 (47)
Age 30-39	51.9,24.5 (44)	57.9, 27.3 (53)	55.2, 26.1 (97)
Age 40-49	43.7, 30.3 (105)	50.7, 27.2 (167)	48.0, 28.6 (272)
Age 50-59	47.0, 23.8 (78)	52.4, 27.2 (286)	51.2, 26.6 (364)
Age 60-69	53.5, 26.3 (39)	60.0, 27.8 (249)	59.1, 27.7 (288)
Age 70-79	57.9, 23.0 (19)	67.5, 25.8 (283)	66.9, 25.7 (302)
Age 80+	61.5, 21.4 (36)	69.2, 24.5 (349)	68.4, 24.3 (385)
For all ages	50.7, 26.8 (348)	61.1, 27.4 (1407)	59.0, 27.6 (1755)
General Health (GH)			
Age 20-29	65.5, 25.5 (27)	65.9, 19.9 (20)	65.7, 23.0 (47)
Age 30-39	59.2, 20.3 (44)	58.0, 24.0 (52)	58.6, 22.3 (96)
Age 40-49	51.3, 26.3 (104)	52.0, 24.3 (165)	51.7, 25.0 (269)
Age 50-59	50.0, 24.4 (78)	51.0, 24.4 (286)	50.8, 24.4 (364)
Age 60-69	59.2, 18.7 (39)	56.3, 21.8 (249)	56.7, 21.4 (288)
Age 70-79	64.4, 19.7 (19)	61.9, 19.7 (281)	62.1, 19.7 (300)
Age 80+	67.6, 16.3 (36)	63.4, 18.5 (345)	63.8, 18.4 (381)
For all ages	56.4, 23.8 (347)	57.8, 22.1 (1398)	57.5, 22.5 (1745)
Vitality (VT)			
Age 20-29	50.7, 24.0 (27)	56.5, 22.5 (20)	53.2, 23.3 (47)
Age 30-39	40.3, 21.1 (44)	55.3, 22.7 (53)	48.5, 23.1 (97)
Age 40-49	37.8, 25.4 (105)	44.5, 25.1 (166)	41.9, 25.4 (271)
Age 50-59	36.7, 22.3 (78)	44.5, 23.7 (286)	42.8, 23.6 (364)
Age 60-69	53.5, 24.4 (39)	52.9, 25.3 (249)	53.0, 25.2 (288)
Age 70-79	50.5, 22.5 (19)	59.6, 22.8 (283)	59.0, 22.8 (302)

	Women	Men	All
Age 80+	50.0, 18.8 (36)	56.5, 21.3 (347)	55.9, 21.2 (383)
For all ages	42.6, 23.9 (348)	52.6, 24.1 (1404)	50.6, 24.4 (1752)
Social Functioning (SF)			
Age 20-29	64.4, 33.0 (27)	80.6, 24.2 (20)	71.3, 30.4 (47)
Age 30-39	65.9, 27.0 (44)	74.1, 30.6 (53)	70.4, 29.2 (97)
Age 40-49	57.2, 32.7 (104)	68.0, 30.7 (167)	63.8, 31.9 (271)
Age 50-59	69.1, 27.1 (78)	69.6, 29.0 (286)	69.5, 28.6 (364)
Age 60-69	78.5, 30.7 (39)	78.7, 24.2 (250)	78.7, 25.1 (289)
Age 70-79	88.8, 21.6 (19)	84.3, 22.2 (282)	84.6, 22.1 (301)
Age 80+	82.3, 18.3 (36)	84.7, 20.7 (347)	84.5, 20.5 (383)
For all ages	68.3, 30.2 (347)	78.0, 26.1 (1405)	76.1, 27.2 (1752)
Role Emotional (RE)			
Age 20-29	67.9, 34.4 (27)	85.0, 21.6 (20)	75.2, 30.6 (47)
Age 30-39	75.3, 27.4 (44)	87.9, 23.0 (53)	82.2, 25.8 (97)
Age 40-49	69.3, 35.5 (104)	74.8, 31.8 (167)	72.7, 33.3 (271)
Age 50-59	70.5, 32.0 (78)	78.6, 28.8 (265)	76.9, 29.7 (363)
Age 60-69	82.7, 26.9 (39)	86.1, 23.8 (250)	85.6, 24.2 (289)
Age 70-79	91.2, 17.9 (19)	91.3, 19.1 (282)	91.3, 19.0 (301)
Age 80+	89.2, 18.6 (36)	92.5, 15.8 (348)	92.2, 16.1 (384)
For all ages	75.0, 31.3 (347)	85.9, 24.3 (1405)	83.7, 26.2 (1752)
Mental Health (MH)			
Age 20-29	64.1, 22.5 (27)	71.6, 20.9 (20)	67.3, 21.9 (47)
Age 30-39	64.4, 21.7 (44)	73.1, 22.5 (53)	69.1, 22.4 (97)
Age 40-49	59.2, 26.8 (105)	66.1, 23.2 (166)	63.4, 24.8 (271)
Age 50-59	65.4, 21.8 (78)	66.5, 22.9 (286)	66.3, 22.6 (364)
Age 60-69	73.6, 20.2 (39)	75.4, 19.9 (249)	75.1, 19.9 (288)
Age 70-79	78.9, 14.6 (19)	80.9, 15.6 (283)	80.8, 15.5 (302)
Age 80+	77.4, 15.5 (36)	81.1, 15.1 (347)	80.8, 15.2 (383)
For all ages	66.2, 23.3 (348)	74.9, 20.3 (1404)	73.1, 21.2 (1752)
Physical Health Composite Score (PCS)			
Age 20-29	47.6, 10.1 (27)	48.6, 8.7 (20)	48.0, 9.5 47
Age 30-39	43.4, 10.7 (44)	42.4, 12.8 (52)	42.9, 11.8 (96)
Age 40-49	38.7, 12.4 (102)	40.2, 11.8 (165)	39.6, 12.0 (267)
Age 50-59	36.7, 12.0 (76)	38.6, 11.8 (285)	38.2, 11.8 (361)
Age 60-69	40.0, 12.0 (39)	40.8, 11.7 (247)	40.7, 11.7 (286)
Age 70-79	39.1, 8.5 (19)	42.7, 10.0 (278)	42.5, 9.9 (297)
Age 80+	39.7,8.7 (36)	42.2, 9.5 (342)	41.9, 9.5 (378)
For all ages	39.8, 11.6 (343)	41.2, 11.0 (1389)	40.9, 11.2 (1732)
Mental Health Composite Score (MCS)			
Age 20-29	43.4, 13.9 (27)	48.8, 10.8 (20)	45.7, 12.8 (47)
Age 30-39	44.5, 11.7 (44)	50.8, 11.9 (52)	47.9, 12.1 (96)
Age 40-49	43.3, 13.9 (102)	46.6, 11.8 (165)	45.4, 12.7 (267)
Age 50-59	47.1, 11.0 (76)	48.2, 11.4 (285)	48.0, 11.3 (361)
Age 60-69	52.1, 10.2 (39)	52.4, 9.6 (247)	52.3, 9.7 (286)
Age 70-79	55.8, 7.4 (19)	55.3, 7.9 (278)	55.3, 7.9 (297)
Age 80+	54.5, 6.8 (36)	55.4, 6.7 (342)	55.3, 6.7 (378)
For all ages	47.2, 12.4 (343)	52.1, 10.1 (1389)	51.1, 10.8 (1732)

Table A.10.a Spearman Correlations between probability of DSM-IV diagnosis assigned by CIDI score and SF36 mental health scales.

		Mental Health Composite Score (MCS)	Mental Health subscale	Role Emotional subscale	Vitality subscale	Social Functioning subscale
CIDI scale		MCS	MH	RE	VT	SF
Major Depression (prob. of case)	Rho P N	-0.52 <.0001 1723	-0.50 <.0001 1739	-0.48 <.0001 1737	-0.41 <.0001 1739	-0.47 <.0001 1738
General Anxiety Disorder (case)	Rho P N	-0.45 <.0001 1701	-0.46 <.0001 1716	-0.47 <.0001 1714	-0.33 <.0001 1716	-0.39 <.0001 1713
Specific Phobia (prob. of case)	Rho P N	-0.25 <.0001 1725	-0.25 <.0001 1741	-0.21 <.0001 1739	-0.23 <.0001 1741	-0.20 <.0001 1739
Social Phobia (prob. of case)	Rho P N	-0.26 <.0001 1719	-0.26 <.0001 1735	-0.27 <.0001 1733	-0.20 <.0001 1735	-0.23 <.0001 1733
Agoraphobia (prob. of case)	Rho P N	-0.23 <.0001 1719	-0.24 <.0001 1735	-0.22 <.0001 1733	-0.20 <.0001 1735	-0.22 <.0001 1733
Panic Disorder (prob. of case)	Rho P N	-0.26 <.0001 1708	-0.24 <.0001 1723	-0.26 <.0001 1722	-0.20 <.0001 1723	-0.24 <.0001 1721
Alcohol Dependence (prob. of case)	Rho P N	-0.17 <.0001 1723	-0.16 <.0001 1739	-0.11 <.0001 1738	-0.07 .0024 1739	-0.13 <.0001 1738
Drug Dependence (prob. of case)	Rho P N	-0.16 <.0001 1712	-0.15 <.0001 1728	-0.16 <.0001 1727	-0.10 <.0001 1728	-0.17 <.0001 1727

Table A.10.b Spearman Correlations between probability of DSM-IV diagnosis assigned by CIDI score and SF36 physical health scales.

		Physical Health score (PCS)	Physical Functioning subscale	Role Physical subscale	Bodily Pain subscale	General Health subscale
CIDI scale		PCS	PF	RP	BP	GH
Major Depression (prob. of case)	Rho P N	-0.22 <.0001 1723	-0.25 <.0001 1739	-0.30 <.0001 1738	-0.36 <.0001 1740	-0.31 <.0001 1736
General Anxiety Disorder (case)	Rho P N	-0.16 <.0001 1701	-0.20 <.0001 1715	-0.26 <.0001 1715	-0.28 <.0001 1717	-0.28 <.0001 1711
Specific Phobia (prob. of case)	Rho P N	-0.11 <.0001 1725	-0.12 <.0001 1741	-0.14 <.0001 1740	-0.18 <.0001 1742	-0.16 <.0001 1737
Social Phobia (prob. of case)	Rho P N	-0.11 <.0001 1719	-0.13 <.0001 1735	-0.15 <.0001 1734	-0.19 <.0001 1736	-0.18 <.0001 1731
Agoraphobia (prob. of case)	Rho P N	-0.13 <.0001 1719	-0.15 <.0001 1735	-0.18 <.0001 1734	-0.17 <.0001 1736	-0.17 <.0001 1731
Panic Disorder (prob. of case)	Rho P N	-0.09 .0003 1708	-0.09 .0002 1723	-0.13 <.0001 1723	-0.18 <.0001 1724	-0.13 <.0001 1719
Alcohol Dependence (prob. of case)	Rho P N	0.02 .36 1723	0.02 .53 1740	-0.02 .36 1739	-0.04 .07 1741	-0.04 .13 1736
Drug Dependence (prob. of case)	Rho P N	-0.04 .07 1712	-0.04 .07 1729	-0.08 .0007 1728	-0.11 <.0001 1730	-0.09 .0002 1725

Table A.11.a Self-Reported Utilization by Age and Gender (MEAN, SD, (N))

	Women	Men	All
Mean Number of Physician Visits (including physical therapy)			
Age 20-29	1.89, 1.28 (27)	1.11, 0.57 (19)	1.57, 1.11 (46)
Age 30-39	1.73, 0.82 (44)	2.49, 4.40 (53)	2.14, 3.31 (97)
Age 40-49	2.38, 2.03 (104)	2.03, 1.50 (164)	2.17, 1.73 (268)
Age 50-59	2.35, 2.43 (78)	2.14, 1.97 (285)	2.19, 2.07 (363)
Age 60-69	2.05, 1.70 (39)	2.32, 2.34 (249)	2.28, 2.27 (288)
Age 70-79	2.47, 2.70 (19)	2.24, 2.02 (282)	2.26, 2.07 (301)
Age 80+	2.39, 1.68 (36)	2.05, 1.54 (346)	2.08, 1.56 (382)
For all ages	2.22, 1.95 (347)	2.16, 2.05 (1398)	2.17, 2.03 (1745)
Mean Number of Days Hospitalized			
Age 20-29	0.00, 0.00 (27)	1.11, 0.00 (19)	0.00, 0.00 (46)
Age 30-39	0.00, 0.00 (43)	0.02, 0.14 (53)	0.01, 0.10 (96)
Age 40-49	0.44, 3.04 (104)	0.15, 1.16 (164)	0.26, 2.10 (268)
Age 50-59	0.28, 2.27 (78)	0.20, 1.62 (285)	0.22, 1.78 (363)
Age 60-69	0.77, 4.80 (39)	0.27, 1.54 (248)	0.34, 2.27 (287)
Age 70-79	0.00, 0.00 (18)	0.26, 2.13 (281)	0.25, 2.07 (299)
Age 80+	0.14, 0.68 (36)	0.06, 0.47 (346)	0.07, 0.49 (382)
For all ages	0.30, 2.56 (345)	0.18, 1.44 (1396)	0.20, 1.72 (1741)
Mean Number of Diagnostic Tests (Laboratory and Radiology)			
Age 20-29	0.81, 0.74 (27)	0.95, 0.91 (19)	0.87, 0.81 (46)
Age 30-39	0.68, 0.67 (44)	0.70, 0.80 (53)	0.69, 0.74 (97)
Age 40-49	1.23, 0.97 (104)	1.02, 0.86 (162)	1.10, 0.91 (266)
Age 50-59	1.05, 0.85 (76)	1.15, 0.87 (283)	1.13, 0.87 (359)
Age 60-69	1.27, 0.96 (37)	1.16, 0.81 (242)	1.17, 0.83 (279)
Age 70-79	1.42, 0.84 (19)	1.24, 0.84 (278)	1.25, 0.84 (297)
Age 80+	1.03, 0.91 (36)	1.16, 0.78 (344)	1.14, 0.79 (380)
For all ages	1.08, 0.89 (343)	1.13, 0.83 (1381)	1.12, 0.85 (1724)

Table A.11.b Self-Reported Utilization by Ethnicity and Gender MEAN, SD (N)

	Women	Men	All
Mean Physician Visits (including physical therapy)			
White	2.21, 1.90 (268)	2.16, 2.05 (1300)	2.17, 2.03 (1568)
African Am	2.31, 2.25 (67)	1.85, 1.38 (81)	2.06, 1.83 (148)
Native Am	2.30, 2.69 (23)	2.47, 4.86 (38)	2.41, 4.15 (61)
Asian Am	2.00, 0.00 (4)	6.67, 6.43 (3)	4.00, 4.47 (7)
Hispanic	1.44, 0.53 (9)	2.50, 2.57 (32)	2.27, 2.31 (41)
Mean Number of Days Hospitalized			
White	0.28, 2.63 (267)	0.18, 1.48 (1298)	0.20, 1.73 (1565)
African Am	0.08, 0.51 (66)	0.15, 0.95 (81)	0.12, 0.78 (147)
Native Am	0.00, 0.00 (23)	0.18, 0.80 (38)	0.11, 0.64 (61)
Asian Am	1.00, 2.00 (4)	0.00, 0.00 (3)	0.57, 1.51 (7)
Hispanic	0.00, 0.00 (9)	0.00, 0.00 (31)	0.00, 0.00 (40)
Mean Number of Diagnostic Tests			
White	1.07, 0.87 (264)	1.14, 0.83 (1285)	1.13, 0.84 (1549)
African Am	1.10, 0.96 (67)	1.04, 0.94 (79)	1.07, 0.94 (146)
Native Am	1.17, 0.94 (23)	1.16, 0.89 (38)	1.16, 0.90 (61)
Asian Am	1.25, 0.50 (4)	1.33, 0.58 (3)	1.29, 0.49 (7)
Hispanic	1.38, 1.06 (8)	1.19, 0.75 (31)	1.23, 0.81 (39)

Table A.12.a Medical Record Report of Utilization by Age and Gender MEAN, SD (N)

	Women	Men	All
Mean Number of Physician Visits (including physical therapy)			
Age 20-29	2.07, 1.66 (27)	2.40, 4.37 (20)	2.21, 3.08 (47)
Age 30-39	2.82, 4.89 (45)	1.53, 1.17 (53)	2.12, 3.46 (98)
Age 40-49	3.36, 4.35 (105)	2.14, 2.27 (167)	2.61, 3.28 (272)
Age 50-59	2.18, 2.15 (78)	2.00, 2.02 (287)	2.04, 2.05 (365)
Age 60-69	2.67, 4.10 (39)	1.53, 1.17 (252)	1.68, 1.88 (291)
Age 70-79	1.53, 0.84 (19)	1.43, 1.02 (283)	1.44, 1.01 (302)
Age 80+	1.25, 0.69 (36)	1.36, 1.14 (350)	1.35, 1.11 (386)
For all ages	2.53, 3.51 (349)	1.65, 1.61 (1412)	1.82, 2.16 (1761)
Mean Number of Prescriptions (all Rx 2 months prior and 1 month after interview)			
Age 20-29	3.70, 5.07 (27)	1.50, 1.73 (20)	2.77, 4.12 (47)
Age 30-39	4.82, 4.96 (45)	4.55, 5.17 (53)	4.67, 5.05 (98)
Age 40-49	9.43, 11.87 (105)	7.57, 7.79 (167)	8.29, 9.59 (272)
Age 50-59	8.67, 7.43 (78)	7.84, 6.92 (287)	8.02, 7.03 (365)
Age 60-69	8.28, 6.35 (39)	7.27, 6.77 (252)	7.41, 6.71 (291)
Age 70-79	6.63, 7.48 (19)	6.56, 4.83 (283)	6.56, 5.02 (302)
Age 80+	8.00, 5.32 (36)	6.00, 4.84 (350)	6.19, 4.91 (386)
For all ages	7.79, 8.54 (349)	6.78, 6.13 (1412)	6.98, 6.69 (1761)
Mean Number of Laboratory Tests			
Age 20-29	7.70, 16.00 (27)	14.55, 22.35 (20)	10.62, 19.05 (47)
Age 30-39	11.18, 20.71 (45)	13.04, 18,96 (53)	12.18, 19.70 (98)
Age 40-49	20.01, 26.03 (105)	15.67, 22.92 (167)	17.35, 24.21 (272)
Age 50-59	17.27, 28.73 (78)	21.40, 24.33 (287)	20.52, 25.35 (365)
Age 60-69	17.59, 20.84 (39)	19.40, 22.77 (252)	19.16, 22.49 (291)
Age 70-79	20.58, 19.18 (19)	22.13, 25.78 (283)	22.03, 25.39 (302)
Age 80+	12.06, 16.70 (36)	20.69, 24.15 (350)	19.88, 23.67 (386)
For all ages	16.25, 23.87 (349)	19.92, 24.02 (1412)	19.20, 24.03 (1761)
Mean Number of Radiology Procedures			
Age 20-29	0.04, 0.19 (27)	0.20, 0.70 (20)	0.11, 0.48 (47)
Age 30-39	0.16, 0.77 (45)	0.17, 0.61 (53)	0.16, 0.68 (98)
Age 40-49	0.36, 0.92 (105)	0.23, 0.82 (167)	0.28, 0.86 (272)
Age 50-59	0.19, 0.70 (78)	0.20, 0.75 (287)	0.20, 0.74 (365)
Age 60-69	0.51, 1.45 (39)	0.14, 0.65 (252)	0.19, 0.81 (291)
Age 70-79	0.00, 0.00 (19)	0.10, 0.45 (283)	0.10, 0.44 (302)
Age 80+	0.11, 0.32 (36)	0.10, 0.44 (350)	0.10, 0.43 (386)
For all ages	0.24, 0.84 (349)	0.15, 0.62 (1412)	0.17, 0.67 (1761)

Table A.12.a continued			
Mean Number of Days Hospitalized			
Age 20-29	0.00, 0.00 (27)	0.00, 0.00 (20)	0.00, 0.00 (47)
Age 30-39	0.07, 0.45 (45)	0.00, 0.00 (53)	0.03, 0.30 (98)
Age 40-49	0.12, 0.83 (105)	0.00, 0.00 (167)	0.05, 0.52 (272)
Age 50-59	0.22, 1.81 (78)	0.02, 0.26 (287)	0.06, 0.87 (365)
Age 60-69	0.00, 0.00 (39)	0.00, 0.06 (252)	0.00, 0.06 (291)
Age 70-79	0.00, 0.00 (19)	0.01, 0.17 (283)	0.01, 0.16 (302)
Age 80+	0.00, 0.00 (36)	0.02, 0.32 (350)	0.02, 0.31 (386)
For all ages	0.09, 0.98 (349)	0.01, 0.21 (1412)	0.03, 0.48 (1761)

Table A.12.b Medical Record Report of Utilization by Ethnicity and Gender MEAN, SD (N)

	Women	Men	All
Mean Number of Physician Visits (including physical therapy)			
White	2.33, 3.18 (268)	1.62, 1.52 (1301)	1.74, 1.92 (1569)
African Am	3.45, 4.73 (67)	2.06, 1.94 (81)	2.69, 3.55 (148)
Native Am	1.91, 1.12 (23)	1.55, 1.27 (38)	1.69, 1.22 (61)
Asian Am	2.50, 1.91 (4)	2.33 2.31 (3)	2.43, 1.90 (7)
Hispanic	2.00, 1.94 (9)	1.81, 1.49 (32)	1.85, 1.57 (41)
Mean Number of Prescriptions (all Rx 2 months prior and 1 month after interview)			
White	8.12, 9.12 (268)	6.86, 6.19 (1301)	7.07, 6.79 (1569)
African Am	7.33, 6.72 (67)	6.17, 5.60 (81)	6.70, 6.14 (148)
Native Am	8.00, 7.52 (23)	7.61, 6.51 (38)	7.75, 6.85 (61)
Asian Am	5.00, 2.94 (4)	8.67, 5.51 (3)	6.57, 4.28 (7)
Hispanic	5.78, 9.27 (9)	7.50, 5.46 (32)	7.12, 6.39 (41)
Mean Number of Laboratory Tests			
White	15.57, 21.65 (268)	20.11, 24.03 (1301)	19.33, 23.69 (1569)
African Am	17.27, 23.09 (67)	18.84, 25.49 (81)	18.13, 24.36 (148)
Native Am	15.22, 17.94 (23)	19.79, 22.56 (38)	18.07, 20.90 (61)
Asian Am	8.25, 10.53 (4)	26.67, 4.16 (3)	16.14, 12.58 (7)
Hispanic	17.22, 25.25 (9)	23.78, 29.29 (32)	22.34, 28.29 (41)
Mean Number of Radiology Procedures			
White	0.24, 0.82 (268)	0.15, 0.63 (1301)	0.16, 0.66 (1569)
African Am	0.24, 0.76 (67)	0.17, 0.57 (81)	0.20, 0.66 (148)
Native Am	0.13, 0.46 (23)	0.29, 0.80 (38)	0.23, 0.69 (61)
Asian Am	0.50, 1.00 (4)	0.00, 0.00 (3)	0.29, 0.76 (7)
Hispanic	0.56, 1.13 (9)	0.31, 1.18 (32)	0.37, 1.16 (41)
Number of Days Hospitalized			
White	0.05, 0.52 (268)	0.01, 0.22 (1301)	0.02, 0.30 (1569)
African Am	0.06, 0.38 (67)	0.00, 0.00 (81)	0.03, 0.26 (148)
Native Am	0.00, 0.00 (23)	0.00, 0.00 (38)	0.00, 0.00 (61)
Asian Am	0.00, 0.00 (4)	0.00, 0.00 (3)	0.00, 0.00 (7)
Hispanic	0.00, 0.00 (9)	0.00, 0.00 (32)	0.00, 0.00 (41)

Appendix B – Meeting abstracts

Abstracts of presentations at meetings, 2005

Poster presented at the meeting of the Associated Professional Sleep Societies, Denver, June, 2005.

Title: Insomnia and Daytime Sleepiness: Risk Attributable to RLS, BMI, Smoking, and Alcohol in a VA Outpatient Population

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Introduction: Insomnia and daytime sleepiness are common among patients with Restless Legs Syndrome (RLS). The goal of this research was to estimate the prevalence of insomnia and daytime sleepiness and to estimate the contribution of RLS and other behavioral factors to these complaints in primary care patients.

Methods: Telephone interviews were conducted with 1761 patients recruited at 12 VA primary care clinics in Ohio. Measures of RLS, insomnia, daytime sleepiness, alcohol dependence, smoking and BMI were included. Logistic regression was used to obtain odds ratios that were used with risk factor prevalence to estimate attributable risks (AR).

Results: Patients were aged 22 to 92. Eighty percent of the sample were male, 41% had a BMI of 30 or over, and 46% had post high school education. The prevalence of RLS symptoms at least once per week was 21% for women and 13% for men. Moderate or severe insomnia was more common in women (27% compared to 14% for men). Both genders had a 7% prevalence of daytime sleepiness. In predicting insomnia, the attributable risk was 22% ($p<.0001$) for RLS, 27% ($p=.003$) for a BMI of 30 or over, 4% ($p=.007$) for alcohol dependence, and 6% ($p=.12$) for smoking. In predicting daytime sleepiness, the AR for insomnia was 27% ($p<.0001$) and 7% ($p=.006$) for RLS. Obesity, smoking, and alcohol dependence did not have a significant relationship to daytime sleepiness beyond their effects on insomnia. Only 10 of the 243 patients who reported RLS symptoms had been diagnosed with RLS.

Conclusion: RLS, obesity, alcohol dependence, and gender, are significant risk factors for insomnia. Insomnia, in turn, is a significant risk factor for daytime sleepiness. RLS is a significant risk factor for daytime sleepiness, even after controlling for insomnia. Despite the impact of RLS on insomnia and daytime sleepiness, few patients are diagnosed with RLS by their physicians.

Supported by DAMD17-03-1-0082 from the US Army Medical Research and Materiel Command and a grant from Pfizer Pharmaceutical Corporation.

Paper presented at the meeting of the Society for Epidemiologic Research, Toronto, Ontario, Canada, June, 2005

Insomnia and Daytime Sleepiness: Risk Attributable to Restless Legs Syndrome, BMI, Smoking, and Alcohol among VA Outpatients.
*C.C. Bourguet, R.P. Steiner, S.K. Ober, K.R. Baughman, H.D. Shapiro. (N. E. Ohio Universities College of Medicine, Rootstown, OH 44272)

Insomnia and daytime sleepiness are common among patients with Restless Legs Syndrome (RLS). This research was planned to estimate the prevalence of insomnia and daytime sleepiness and to estimate the contribution of RLS and other behavioral factors to these complaints in primary care patients.

Telephone interviews were conducted with 1761 patients recruited at 12 VA primary care clinics in Ohio. Measures of RLS, insomnia, daytime sleepiness, alcohol dependence, smoking and BMI were included. Logistic regression was used to obtain odds ratios that, with risk factor prevalence, estimated attributable risks (AR).

Patients were aged 22 to 92. Eighty percent of the sample were male, 41% had a BMI of 30 or over, and 46% had post high school education. The prevalence of RLS symptoms at least once per week was 21% for women and 13% for men. Moderate or severe insomnia was more common in women (27% compared to 14% for men). Both genders had a 7% prevalence of daytime sleepiness. In predicting insomnia, the attributable risk was 22% ($p<.0001$) for RLS, 27% ($p=.003$) for a BMI of 30 or over, 4% ($p=.007$) for alcohol dependence, and 6% ($p=.12$) for smoking. In predicting daytime sleepiness, the AR for insomnia was 28% ($p<.0001$) and 7% ($p=.006$) for RLS. Obesity, smoking, and alcohol dependence did not have a significant relationship to daytime sleepiness beyond their effects on insomnia. Only 10 of the 243 patients who reported RLS symptoms had received a diagnosis.

RLS, obesity, alcohol dependence, and gender, are significant risk factors for insomnia. Insomnia, in turn, is a significant risk factor for daytime sleepiness. RLS is a significant risk factor for daytime sleepiness, even after controlling for insomnia. Despite the impact of RLS on insomnia and daytime sleepiness, few patients are diagnosed with RLS by their physicians.

Supported by the US Army Medical Research and Materiel Command and Pfizer Pharmaceutical Corporation.

Abstracts presented at scientific meetings in 2003 and 2004 (included in Year 1 and Year 2 report).

Presented at the meeting of the Associated Professional Sleep Societies in Philadelphia, June, 2004.

The Prevalence and Outcomes of Restless Legs Syndrome among Veterans.
Ober SK, Bourguet CC, Baughman KR, Steiner RP, and Shapiro, HD.

Introduction: Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest or when initiating sleep, and in the evening or at night. Sufferers experience an uncontrollable urge to move to relieve these symptoms. RLS interferes with the ability to fall asleep or maintain sleep. Estimates of the prevalence of RLS in community populations ranges from 4% to 17%. A 29% prevalence has been reported in one VA outpatient sample. The goal of this research is to estimate the prevalence of RLS and insomnia among patients seen at VA primary care clinics. This research investigates an explanatory model in which RLS contributes to insomnia. Insomnia contributes to diminished mental health status and to increased health care utilization. **Methods:** Study members were a representative sample of Veterans seen at Community Based Outpatient Clinics affiliated with the Louis B. Stokes Cleveland VA Medical Center in Ohio. A cross-sectional telephone survey was used to determine the prevalence of RLS and insomnia. Patients were classified as non-RLS cases, probable (3 criteria) or definite (4 criteria) cases. Health status was measured using the Mental and Physical Composite Scales (MCS and PCS) of the SF12. Utilization information was obtained from the patient and included: number of office visits, diagnostic procedures, hospitalizations, and surgical procedures. All tests of hypothesized relationships were adjusted for age, gender, Body Mass Index, and physical health status (PCS score). **Results:** Preliminary results from 620 patients are reported. Forty-five percent of patients who were approached completed an interview. The sample included 544 men and 76 women, age range 25 to 89 years. Among men, the prevalence of probable RLS was 15.8%, definite RLS was 9.7%, moderate insomnia was 9.9% and severe insomnia was 3.3%. Among women, the prevalence of probable RLS was 19.7%, definite RLS was 14.5%, moderate insomnia was 26.3%, and severe insomnia was 7.9%. The insomnia score of an average patient increased 53% in the presence of 4 RLS symptoms ($p < .001$). In this VA sample, the mean MCS score was 50.3, similar to the US population mean. The mean PCS score was 39.9, one standard deviation below the US mean. The mean MCS score of persons with probable or definite RLS was significantly lower (41.0, $p<.01$), as was the mean MCS score of persons with moderate insomnia (40.6, $p <.0001$) and of persons with severe insomnia (34.7, $p<.0001$). As hypothesized, the association between RLS and the MCS disappeared when insomnia was included in the regression model. Analysis of utilization data obtained from patients found that neither insomnia nor RLS were associated with physicians visits. RLS but not insomnia was positively associated ($p = .04$) with diagnostic testing. **Conclusions:** Preliminary analysis of approximately one third of the planned sample offered support for the hypothesized explanatory model. The final sample (n=1914) will allow precise estimates of RLS prevalence in age strata. **Support:** Supported by the US Army Medical Research and Materiel Command under DAMD17-03-1-0082.

Abstract presented at the Peer Reviewed Medical Research Program Military Health Research Forum (Investigators' Meeting), San Juan, Puerto Rico, April, 2004.

THE PREVALENCE AND OUTCOMES OF RESTLESS LEGS SYNDROME AMONG VETERANS. Bourguet CC, Ober SK, Baughman KR, Steiner RP, Shapiro, HD. The Northeastern Ohio Universities College of Medicine.

BACKGROUND/ PURPOSE: Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest or when initiating sleep, and in the evening or at night. The sufferer experiences an uncontrollable urge to move in order to relieve these symptoms. RLS interferes with the ability to fall asleep or maintain sleep. Estimates of the prevalence of RLS in community populations ranges from 4% to 17%. A 29% prevalence has been reported in one VA outpatient sample. The goal of this research is to estimate the prevalence of RLS and insomnia among patients seen at VA primary care outpatient clinics. This research investigates an explanatory model in which RLS contributes to insomnia. Insomnia contributes to diminished mental health status, and diminished mental health status leads to increased health care utilization. **METHODS:** Study members are a representative sample (final sample size = 1914) of Veterans seen at Community Based Outpatient Clinics affiliated with the Louis B. Stokes Cleveland VA Medical Center in Ohio. A cross-sectional telephone survey is being used to determine the prevalence of RLS and insomnia. Patients are classified as non-RLS cases, probable (3 criteria) or definite (4 criteria) cases. Health measures include the Mental and Physical Composite Scales (MCS and PCS) of the SF12, the WHO's Composite International Diagnostic Index (Short Form), and the problem list from the medical record. Utilization measures will be obtained from the patient and the medical record and include: number of office visits, diagnostic procedures, prescribed medications, hospitalizations, and surgical procedures. Additional utilization data will be collected at one year follow-up. All data analysis includes adjustment for age, gender, Body Mass Index, and physical health status (PCS score). **RESULTS:** Preliminary results from 620 patients are reported here. Forty-five percent of patients who were approached completed an interview. The sample includes 544 men and 76 women, age range 25 to 89 years. Among men, the prevalence of probable RLS is 15.8%, definite RLS is 9.7%, moderate insomnia is 9.9% and severe insomnia is 3.3%. Among women, the prevalence of probable RLS is 19.7%, definite RLS is 14.5%, moderate insomnia is 26.3%, and severe insomnia is 7.9%. The insomnia score of an average patient increases 53% in the presence of 4 RLS symptoms ($p < .001$). In this VA sample, the mean MCS scores is 50.3, similar to the US population mean. The mean PCS score is 39.9, one standard deviation below the US mean. The mean MCS score of persons with probable or definite RLS is significantly lower (41.0, $p<.01$), as is the mean MCS score of persons with moderate insomnia (40.6, $p < .0001$) and of persons with severe insomnia (34.7, $p<.0001$). As hypothesized, the association between RLS and the MCS disappears when insomnia is included in the regression model. Analysis of utilization data obtained from patients finds that neither insomnia nor RLS is associated with physicians visits. RLS but not insomnia is positively associated ($p=.04$) with diagnostic testing. **CONCLUSION:** Preliminary analysis of approximately one third of the planned sample offers support for the hypothesized explanatory model. The final sample will allow precise estimates of RLS prevalence in age strata. Data obtained from medical records will allow improved adjustment for health status and more definitive conclusions about the relationship between sleep disorders and health care utilization.

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The Prevalence and Outcomes of Restless Legs Syndrome among Patients at VA Primary Care Clinics. Baughman K., Panzner M., Ober S., Bourguet C., Steiner R. Louis Stokes Department of Veterans Affairs Medical Center, Brecksville, OH 44141

Introduction: Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest or when initiating sleep, and in the evening or at night. RLS interferes with the ability to fall asleep or maintain sleep. The goal of this research is to estimate the prevalence of RLS and insomnia among patients seen at VA primary care clinics. This research investigates an explanatory model in which RLS contributes to insomnia. Insomnia contributes to diminished mental health status and to increased health care utilization. **Methods:** Study members were representative of Veterans seen at primary care clinics affiliated with the Cleveland VA Medical Center. A telephone survey was used to determine the prevalence of RLS and insomnia. Patients were classified as non-RLS cases, probable or definite cases. Health status was measured using the Mental and Physical Composite Scales (MCS and PCS) of the SF12. Utilization information was obtained from the patient and included: number of office visits, diagnostic procedures, hospitalizations, and surgical procedures. All tests of hypothesized relationships were adjusted for age, gender, Body Mass Index, and physical health status (PCS score). **Results:** Preliminary results from 620 patients are reported. Forty-five percent of patients who were approached completed an interview. The sample included 544 men and 76 women, age range 25 to 89 years. Among men, the prevalence of probable RLS was 15.8%, definite RLS was 9.7%, moderate insomnia was 9.9% and severe insomnia was 3.3%. Among women, the prevalence of probable RLS was 19.7%, definite RLS was 14.5%, moderate insomnia was 26.3%, and severe insomnia was 7.9%. The insomnia score of an average patient increased 53% in the presence of definite RLS ($p < .001$). The mean MCS score was 50.3, similar to the US population mean. The mean PCS score was 39.9, one standard deviation below the US mean. The mean MCS score of persons with probable or definite RLS was significantly lower (41.0, $p<.01$), as was the mean MCS score of persons with moderate insomnia (40.6, $p <.0001$) and of persons with severe insomnia (34.7, $p<.0001$). As hypothesized, the association between RLS and the MCS disappeared when insomnia was included in the regression model. Analysis of utilization data obtained from patients found that neither insomnia nor RLS was associated with physicians visits. RLS but not insomnia was positively associated ($p = .04$) with diagnostic testing. **Conclusions:** Preliminary analysis of approximately one third of the planned sample offered support for the hypothesized model in which RLS impacts health outcomes and utilization through insomnia. **Support:** Supported by the US Army Medical Research and Materiel Command under DAMD17-03-1-0082.